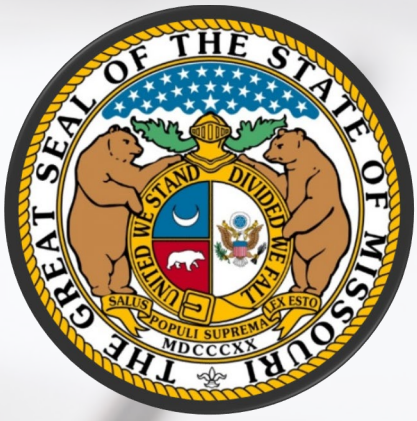
MISSOURI PHARMACY PRACTICE GUIDE

2023



MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the updated *2023 Missouri Pharmacy Practice Guide*. The Pharmacy Practice Guide is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing pharmacypractice.

The Board has served Missouri citizens through the regulation and licensing of the pharmacy profession since 1909. The Board is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Commerce and Insurance. The Board's mission is to serve and protect the public in the practice of pharmacy by providing an accessible, responsible and accountable regulatory system that:

- Protects the public;
- Licenses only qualified professionals; and
- Enforces practice standards.

The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri.

Additional pharmacy resources and compliance materials are available on the Board's website at pr.mo.gov/pharmacists. The Board also provides license and regulatory updates via e-alerts and the Board's electronic newsletter. Interested parties can sign up for the Board's newsletter and e-alerts at https://public.govdelivery.com/accounts/MODIFP/subscriber/new.

The Missouri Pharmacy Practice Guide is provided for *informational purposes only* and does not constitute a rule statement of general applicability or binding law. Additionally, the Practice Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should independently review Chapter 338, RSMo, 20 CSR 2220 and all applicable state and federal laws. Statutes/rules may have changed since this document was issued. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The term "should" represents Board/staff recommendations. Questions regarding the Practice Guide can be e-mailed to MissouriBOP@pr.mo.gov.

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A.1 BOARD AUTHORITY

Pursuant to Chapter 338, of the Revised Statutes of Missouri, the Board has regulatory authority over the practice of pharmacy in Missouri which includes, but is not limited to, regulating and licensing pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers. The Board's administrative rules are promulgated in Chapter 20 CSR 2220 of the Missouri Code of State Regulations.

- The Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") regulates controlled substance distribution in Missouri. However, the Board monitors and inspects compliance with applicable controlled substance drug laws. For controlled substance questions, contact BNDD at (573) 751-6321 or e-mail bndd@health.mo.gov. *E-mail is preferred.*
- The Missouri Department of Health and Senior Services (DHSS) has regulatory jurisdiction over pharmacy services provided within the "licensed premises" of a Missouri hospital (see Chapter 197). However, Class-B hospital pharmacies are under the Board's jurisdiction (see D.10). DHSS related hospital questions should be addressed to (573) 751-6303 or HSRelectronic2567@health.mo.gov.

A.2 COMPLIANCE AND EDUCATION

The Board is committed to promoting voluntary compliance through education and awareness. A variety of free practice resources are available on the Board's website including:

1. Brochures/Compliance Guides: Brochures on a variety of compliance topics are available online at https:// pr.mo.gov/pharmacists-publications-resources.asp, including, Inspector Tips for Preventing Drug Diversion, theCompliance Top 10, the Pharmacist Immunization/Administration Checklist and the Pharmacy Self-AssessmentGuide. Resources are also available for technicians such as the Technician Compliance Guide and a free online Technician Quiz.
2. Webinars: The Board periodically hosts free webinars to discuss emerging compliance issues and trends. Pharmacist CE is available for attending live webinars. Recorded webinars are available on the Board's website for on-demand review at http://pr.mo.gov/pharmacists-publications-resources.asp#videos.
3. Newsletters/E-Alerts: Sign-up for the Board's newsletter and e-alerts at public.govdelivery.com/accounts/MODIFP/subscriber/new to receive webinar notices and other regulatory updates, including, notification of technician disciplinary actions.

A.3 DISCIPLINARY AUTHORITY

The Board may impose discipline if a licensee/registrant, or any officer, owner, pharmacist-in-charge or manager-in-charge, has committed any act identified in § 338.055.2. Grounds for disciplinary action include, but are not limited to:

1. Using a controlled substance or alcoholic beverage to an extent that such use impairs a licensee's/registrant's ability to practice;
2. Being finally adjudicated and found guilty, or entering a plea of guilty or nolo contendere, for any criminal offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated by Chapter 338, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude (this includes a suspended imposition of sentence or "SIS");
3. Obtaining or attempting to obtain any fee or other compensation by fraud, deception or misrepresentation;
4. Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance

of the functions or duties of any profession licensed or regulated by Chapter 338;
5. Violating, or assisting or enabling any person to violate, Chapter 338 or any Board rule;
6. Assisting or enabling any person to practice or offer to practice without the required Board license, registration or permit;
7. Violating any professional trust or confidence;
8. Violating state or federal drug laws/regulations;
9. Intentionally substituting or changing the content, formula or brand of any drug prescribed without prior prescriber approval; or
10. Using any controlled substance unless it is prescribed, dispensed, or administered by an authorized health care provider. *See § 338.055 for a list of all disciplinary grounds*.

Disciplinary action may include, but is not limited to, public censure, probation, suspension or revocation. If revoked, the Board may prohibit a licensee from reapplying for licensure for up to seven (7) years.

Compliance cases are reviewed on a case-by-case basis. The Board considers multiple factors when reviewing a disciplinary case, including, but not limited to:

- The nature, severity, and frequency of the conduct
- The relationship of the conduct to the profession
- When the conduct occurred
- Evidence of rehabilitation, including, the progress/conduct of the licensee since the incident and any corrective actions taken
- Motive
- Acknowledgement of conduct
- Victim harm and any threat/risk posed to the public
- Acknowledgement of conduct, and
- Length of licensure.

A.4 BOARD INVESTIGATIONS

Licensees, permit holders and Board registrants must cooperate with any investigation or inspection conducted by or on the Board's behalf [20 CSR 2220-2.010(7)]. Cooperation includes responding fully and promptly to questions, providing copies of records as requested, executing releases for records as requested, allowing photographs or digital image capture of any facility licensed or permitted by the board, and appearing at interviews, hearings, or meetings scheduled by the board or the board's authorized designee. Failure to cooperate constitutes grounds for disciplinary action under Missouri law.

B.1 GENERAL REQUIREMENTS

No person may perform, or offer to perform, the practice of pharmacy in the state of Missouri without a current and active Missouri pharmacist license. (See § 338.010.1 or Section C.1 for the definition of "*practice of pharmacy*"). A pharmacist license is not required for legally registered practitioners of medicine, dentistry, podiatry, veterinary medicine or optometry that are lawfully compounding or dispensing their own prescriptions. [§ 338.010.1]

In addition to a Missouri pharmacist license, additional certification and/or Board notification is required for pharmacists performing the following services:

- Administering Medication By Prescription Order (See Section L)
- Immunizing by Protocol (see Section M)
- Medication Therapy Services (See Section N)

B.2 NAME, ADDRESS & EMPLOYMENT CHANGES

The following requirements apply to all Missouri licensed pharmacists:

- Name Changes: Name changes must be submitted to the Board in writing along with legal documentation of the change (e.g., marriage certificate, court order, divorce order). Once received, your name will be officially changed in the Board records. A Duplicate License Request application should be submitted if you would like your pharmacist license to be reissued under the new name (applications are online; fees will apply).
- Address & Employment Changes: Address & employment changes must be submitted to the Board no later than fifteen (15) days after the change. [20 CSR 2220-2.010(1)(Q)]. Changes can be submitted online at https://pr.mo.gov/pharmacists-coa.asp.

B.3 RENEWALS/CONTINUING EDUCATION

Pharmacist licenses must be renewed by October 31st of every even numbered year (e.g., 2024, 2026, 2028). To renew,pharmacists must file a renewal application with the required fee and complete 30 hours of approved continuing education (CE) (or 3.0 CE units). [20 CSR 2220-7.080].

CE must have been earned from November 1st and October 31st of the current even-numbered renewal years. For example,licensees renewing in 2024 must have completed 30 CE hours between November 1, 2022, to October 31, 2024. Although the CE deadline is October 31st, CE must be completed before a renewal is submitted. CE may not be carried over from prior renewal years.

Eligible CE must be provided by either an ACPE accredited provider or approved by the Board in advance. The following non-ACPE classes/courses are eligible for approval **if pre-approved by the Missouri Board of Pharmacy**:

1. CE courses/programs offered by a state, federal or local governmental or regulatory agency;
2. Courses/programs that relate to the practice of pharmacy; and
3. Training in suicide assessment, referral, treatment and/or management pre-approved, or
4. Post-graduate college credits earned at an accredited pharmacy, medical, or dental educational institution of higher learning (see 20 CSR 2220-7.080(6)). CE credit will only be granted for post-graduate courses/classes. College courses/classes taken as part of your initial pharmacist degree curriculum are not eligible for CE credit.

The following non-ACPE classes/courses are also eligible for approval (pre-approval by the Board is not required):

1. CE courses/programs offered or provided by the Missouri Board of Pharmacy (e.g., Board webinar), and
2. Post-graduate college credits earned at an accredited pharmacy, medical, or dental educational institution of higher learning (see 20 CSR 2220-7.080(6)). CE credit will only be granted for post-graduate courses/classes. College courses/classes taken as part of your initial pharmacist degree curriculum are not eligible for CE credit.

Applications to approve a non-ACPE accredited course are available online at: pr.mo.gov/boards/pharmacy/375-0419.pdf and should be submitted at least thirty (30) days prior to the date of the program. Only non-ACPE courses have to be pre-approved. The Board will not approve non-ACPE classes that have already been taken.

Missouri law does not require continuing education in specific categories, except for pharmacists who are:

- Immunizing by protocol (*See Section M*)
- Providing medication therapy services (*See Section N*), or
- Counseling bleeding disorder patients (*See D.14*)

Licensees should review 20 CSR 2220-7.080 for a complete listing of Missouri CE requirements. A CE Compliance Chart is also provided below. The Board randomly audits CE compliance. Proof of CE must be maintained in the licensee's records for two renewal cycles and provided on request.

Pharmacists must attest that their CE is complete as part of the renewal application. Submitting a false attestation is grounds for discipline. Do not renew online or submit a paper application until your CE is complete. If CE is not complete by the end of the renewal period, pharmacists can choose to go inactive until the required CE is finished. Please contact the Board office for additional information on going inactive. Inactive licensees are not eligible to practice.

MISSOURI PHARMACIST CONTINUING EDUCATION REQUIREMENTS

Who?	Number of hours	CE DATE RANGE	Can I use it as part of my 30 hours?	Notes
All Missouri licensed pharmacists (In-state & out-of-state) [20 CSR 2220-7.080]	30	11/1 - 10/31 of EVEN numbered years (e.g., Nov. 1, 2022 - Oct. 31, 2024; Nov. 1, 2024 - Oct. 31, 2026)	Yes	
Pharmacists dispensing/providing patient counseling on blood clotting factor concentrates [20 CSR 2220 - 6.100(3)]	4 hours of approved CE related to blood clotting factor concentrates, infusion treatment or therapy or blood clotting disorders or diseases	11/1 - 10/31 of even numbered years (e.g., Nov. 1, 2022 - Oct. 31, 2024; Nov. 1, 2024 - Oct. 31, 2026)	Yes	The CE requirement only applies to certain pharmacists dispensing blood clotting factor concentrates and pharmacists who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients. See 20 CSR 2220-6.100(3) for definitions of "blood-clotting product" and a "bleeding disorder patient" and for more information on who needs to comply.
Pharmacist Immunizing by Protocol [20 CSR 2220-6.050(3)	2 hours of approved CE related to administering vaccines or CDC immunization guidelines	11/1 - 10/31 of even numbered years (e.g., Nov. 1, 2022 - Oct. 31, 2024; Nov. 1, 2024 - Oct. 31, 2026)	Yes	CE may also be used to satisfy your biennial pharmacist CE requirements; Notifications of Intent to Immunize by Protocol can be renewed with your pharmacist license.
Pharmacists with a Certificate of Medication Therapeutic Services ("MTS Certificate) [20 CSR 2220-6.070]	6 hours of approved CE related to medication therapy management	11/1 - 10/31 of even numbered years (e.g., Nov. 1, 2022 - Oct. 31, 2024; Nov. 1, 2024 - Oct. 31, 2026)	Yes	The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Disease State Management/Drug Therapy ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).
Intern Pharmacists/ Pharmacy Technicians	NO CE REQUIREMENTS	NO CE REQUIREMENTS	N/A	

Suicide Prevention: Section 324.046 provides training in suicide assessment, referral, treatment and management may qualify for pharmacist continuing education credit. However, non-ACPE accredited courses must be pre-approved by the Board. Credit will not be given for courses taken before the Board approves them. CE in suicide prevention is recommended by the Board but not required.

B.4 INACTIVE LICENSES [20 CSR 2220-7.080(9)]

Pharmacists may only place their license on inactive status during the biennial pharmacist renewal period and cannot request to go inactive at any other time. Once processed, an inactive pharmacist license will be issued by the office. Inactive licenses must be renewed biennially; Continuing education (CE) is not required to renew as inactive. Inactive licensees may not practice pharmacy in the state of Missouri. However, inactive licensees are still eligible for the 50-year gold certificate.

To return to active status, licensees must file an application with the Board and submit proof of the required CE for each renewal period that the licensee was inactive. For example, licensees who are inactive for three renewal periods must submit proof of ninety (90) hours of CE (30-hours for each renewal period).

B.5 JURY DUTY

Section 494.430.1(5), RSMo, allows a pharmacist to be excused from jury duty if he/she is providing health care services to patients and serving as a juror would be detrimental to patient health. This exemption is not automatic and must be granted by a judge.

B.6 MILITARY LICENSEES

A Missouri pharmacist license is not required for pharmacists serving in the United States armed forces, or pharmacists employed by the U.S. government or any U.S. agency/bureau, who are engaged in the practice of pharmacy while in the discharge of their official duties. This exemption only applies to pharmacy services provided as part of the pharmacist's federal/military duties or employment. A Missouri pharmacy license is required if the pharmacist is practicing outside of his/her federal or military duties (e.g., independently practicing at a retail pharmacy). [§ 338.020.2, RSMo]

Late Renewals/CE Exemption: A pharmacist may renew his/her license for no fee if the pharmacist's license expired while on active duty in the U.S. armed services/Coast Guard/state militia, or expired while in training or education prior to being inducted into the military. [Section § 338.060.2] Renewal applications must be submitted within one (1) year after terminating the applicable military service, training or education. Section 41.946, RSMo, waives Missouri's CE requirements for licensees whose license expired while completing military service.

To submit a late renewal or to request a CE exemption, pharmacists must provide an affidavit attesting that the pharmacist was engaged in military service as provided by § 338.060.2, RSMo. Alternatively, the Board will accept official discharge documentation that includes:

- The pharmacist's name,
- The date service/training/education began and ended, and
- The status of termination (e.g., completed, honorably discharged, etc.). *Note: The late renewal allowance does not apply if dishonorably discharged.*

For questions about military renewals/licensing, e-mail pharmacist@pr.mo.gov. Additional resources for military service members are available on the Board's website at: https://www.pr.mo.gov/boards/VeteransServicesandBenefits.pdf

- *Exam Reimbursement: Veterans may be eligible for reimbursement from Veterans Affairs for the Board's licensing exam fees. Visit the Veterans Affairs website to learn more about how the GI Bill can pay the cost of a license or certification test or call 888-GIBILL-1 (888-442-4551), or for the hearing-impaired call 800-829-4833.*
- *Military Spouses: A non-resident spouse of an active duty member of the U.S. Armed Forces may apply for a temporary pharmacist license to practice in Missouri, if the applicant is domiciled in Missouri or theirspouse has transferred/moved to Missouri, or will be transferring or moving to Missouri, as part of their military service (permanently or temporarily). Non-resident military spouses applying for a temporary pharmacist license must hold an active pharmacist license from another U.S. state or territory. No application fees will apply. Temporary pharmacist licenses are valid for six (6) months. For additional information, see rule 20 CSR2220-7.075 or contact pharmacists@pr.mo.gov.*

B.7 REPORTING DISCIPLINARY/ADVERSE ACTIONS

Pharmacists must self-report the following to the Board within fifteen (15) days:

1. Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer or drug outsourcing facility,
2. Any surrender of a license or authorization to practice as a pharmacist, pharmacy, drug distributor, drug manufacturer, pharmacy technician, intern pharmacist or drug outsourcer, and
3. Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet). [§ 338.075; 20 CSR 2220-2.010(4)]

Notification can be submitted on the Board's website using the Discipline/Adverse Action Reporting Form. Each report is reviewed on a case-by-case basis to determine if further review or action is necessary. An investigation may not be initiated in every case. Licensees will be contacted if additional information is needed.

B.8 BOARD INVESTIGATIONS

Licensees must cooperate with any investigation or inspection conducted by or on the Board's behalf. [20 CSR 2220-2.010(7)] Cooperation includes responding fully and promptly to questions, providing copies of records as requested, executing releases for records as requested, allowing photographs or digital image capture of any facility licensed or permitted by the board, and appearing at interviews, hearings, or meetings scheduled by the board or the board's authorized designee. Failure to cooperate constitutes grounds for disciplinary action under Missouri law.

C.1 AUTHORIZED ACTIVITIES

A Missouri licensed pharmacist may perform any act within the scope of the practice of pharmacy as defined by § 338.010, RSMo, which includes:

- *Consulting with patients and other health care practitioners about the safe and effective use of drugs and devices, including, providing patient education;*
- *Interpreting, implementing, and evaluating prescriptions/medication orders;*
- *Handling or facilitating dispensing;*
- *Compounding or dispensing medication pursuant to a prescription/medication order;*
- *Participating in drug selection and drug utilization reviews;*
- *Prescribing nicotine replacement therapy products as defined by § 338.665, RSMo;*
- *Executing state-issued standing orders as authorized by law;*
- *Providing medication therapy services;***
- *Administering vaccines by protocol***
- *Administering medication by prescription drug order; and***
- *Offering or performing any act or service necessary in the conduct, operation, management and control of a pharmacy. [§ 338.010]*

*****See sections L-N for additional training/requirements.***

Pharmacy services must be safely and competently provided at all times. Pharmacists should know and practice within their education, training and experience and in compliance with applicable state and federal law.

C.2 STAFF SUPERVISION

Pharmacy technicians and intern pharmacists must be properly supervised at all times to ensure delegated activities are properly performed in compliance with state/federal law. Supervision requirements will vary based on practice setting/activities; Technology assisted-supervision is authorized in some instances (see C.3 for Technology Assisted Supervision). The supervising pharmacist remains responsible for delegated tasks, regardless of practice location or supervision method.

The information in this section applies to a Missouri-licensed pharmacy that is not a Class F (Renal Dialysis), Class L (Veterinarian), Class Q (Charitable) or Class R (Remote Dispensing Site) pharmacy. See the following rules/ Practice Guide sections for supervision requirements applicable to the following activities/pharmacysettings:

- Class F: Renal Dialysis Pharmacies (20 CSR 2220-2.600)
- Class L: Veterinary pharmacies (see D.13/20 CSR 2220-2.675)
- Class Q: Charitable Pharmacies (see D.15/20 CSR 2220-2.685)
- Class R: Remote Dispensing Sites (D.16/20 CSR 2220-2.680)
- Remote data entry sites (see H.3, 20 CSR 2220-2.725), and
- Non-dispensing activities outside of a pharmacy (see C.5/20 CSR 2220-6.055)

Supervision At A Missouri-Licensed Pharmacy:

Except as otherwise authorized for Class F Renal Dialysis pharmacies, Class L Veterinary pharmacies, Class Q charitable pharmacies, and Class R Remote Dispensing Site pharmacies, pharmacy technicians/ intern pharmacists assisting with pharmacy practice at a Missouri-licensed pharmacy must be under the direct supervision of a Missouri-licensed pharmacist who is "readily and immediately available" to render immediate assistance and able to identify or correct any errors before final dispensing. [338.010.1; 20 CSR 2220-2.010(1)(B), 20 CSR 2220-2.710(1)]

"Readily and immediately available" means the supervising pharmacist must either be on the same physical premises as the pharmacy technician/intern pharmacist when supervising, or must supervise pharmacy technician/intern activities using technology that complies with 20 CSR 2220-2.710. The supervising pharmacist is responsible for ensuring full compliance with Missouri law, regardless of supervision method chosen (in-person or remote/technology-assisted). ****See C.3 for Technology Assisted Supervision Requirements****

Final prescriptions and the affixed labels must be verified by a pharmacist either personally or via an authorized electronic verification system (see H.4 and H.5). Effective August 28, 2022, rule 20 CSR 2220-2.012 allows a qualified pharmacy technician or qualified intern pharmacist to verify non-controlled prescriptions/orders using a technology assisted verification system, if allowed by a Missouri licensed pharmacist (see H.6) A Missouri-licensed pharmacist must verify the accuracy of prescription/medication order data entered into an electronic prescription system by a pharmacy technician or intern pharmacist prior to dispensing for all prescriptions/medication orders, even if technology assisted verification is used. [20 CSR 2220-2.017(1), 20 CSR 2220-2.080(1)].

Pharmacy staff must terminate activities if a Missouri-licensed pharmacist is not supervising as required by 20 CSR 2220-2.010 and 20 CSR 2220-2.710 (in-person or via technology). To assist patients, the Board has determined technicians/intern pharmacists may accept written prescriptions at a pharmacy when a pharmacist is not supervising (in-person or via technology), but cannot take verbal prescription orders or otherwise assist with pharmacy practice.

"No Pharmacist On Duty Sign": A sign notifying the public that "no pharmacist is on duty" must be manually or electronically posted on the prescription counter and on all entrance doors if a pharmacist is not physically present at the pharmacy and personally supervising. [20 CSR 2220-2.010(1)(A)]. Sign lettering must be at least two (2) inches in height. The "no pharmacist on duty" sign is required even if the pharmacy is being remotely supervised using technology.

- The Board has determined the "no pharmacist on duty" sign does not have to be posted if thepharmacist is briefly absent from the pharmacy area (e.g., a restroom break).

Example of Supervision Allowed by 20 CSR 2220-2.010 and 2220-2.700:

- The supervising pharmacist is administering a vaccine at the pharmacy but is available to answer pharmacy technician/intern pharmacist questions and to assist with/direct pharmacy technician activities, if needed.

Examples of Supervision **Not** Allowed By 20 CSR 2220-2.010 and 2220-2.700:

- A pharmacist is at lunch on the pharmacy's premises but has asked not to be interrupted and is not available to answer questions from pharmacy staff. The pharmacist is not readily available under 20 CSR 2220-2.010 and 2220-2.700 and pharmacy technician/intern pharmacist activities must terminate until the pharmacist is able to directly supervise in compliance with the rule (the no pharmacist on duty sign must also be posted).
- The staff pharmacist is running late and the pharmacist-in-charge has authorized pharmacy staff to dispense prescriptions in the will-call bin that were previously verified by a pharmacist. Pharmacy technicians/intern pharmacists ***cannot*** compound, prepare, dispense or provide medication unless a pharmacist is physically present in the dispensing area.

C.3 TECHNOLOGY-ASSISTED SUPERVISION

Rule 20 CSR 2220-2.710(2)(A) allows a Missouri licensed pharmacist to supervise pharmacy technicians and intern pharmacists assisting in the practice of pharmacy using technology provided:

- The technology allows the supervising pharmacist to communicate with and monitor pharmacy technicians/intern pharmacists in a manner that is sufficient to provide the personal assistance, direction, and approval needed to verify and ensure delegated tasks are safely and properly performed. [20 CSR 2220-2.710(2)(A)] The Board recommends two-way video and audio capability as a best practice, however, video capability is not required unless deemed appropriate by the supervising pharmacist/permit holder.
- Licensees must comply with all applicable state and federal laws, including, all privacy and confidentiality laws.
- Pharmacy technicians/intern pharmacists being supervised via technology must have completed employer approved training in the activities performed and must have a documented initial and annual competency assessment. The form and content of the required training/assessment is in the pharmacy's discretion. Proof of compliance must be maintained in the pharmacy's records for at least two (2) years. [20 CSR 2220-2.710(2)(C)]
- An audit trail must be maintained by the permit holder and supervising pharmacist of any prescription/medication order data entry or modifications to a patient record made by a technician/intern pharmacist while being supervised via technology. The required records must include the identity of the technician/intern pharmacist and must be maintained for a minimum of five (5) years (e.g., initials, user code). [20 CSR 2220-2.710(2)(D)].

Technology-assisted supervision is NOT allowed if pharmacy technicians/intern pharmacists are administering medication/vaccines, or compounding, preparing or dispensing medication. [20 CSR 2220-2.010(1)(A) and (B)] A licensed pharmacist must be physically present within the confines of the dispensing area and able to render immediate assistance whenever medication is administered, compounded, prepared or dispensed, except as otherwise authorized for Class F Renal Dialysis pharmacies, Class L Veterinary pharmacies, Class Q Charitable pharmacies, and Class R Remote Dispensing Site pharmacies.

Licensees should use their discretion when selecting technology and are reminded that the supervising pharmacist, pharmacist-in-charge, and permit holder will be held jointly and individually responsible for ensuring compliance. Technology-assisted supervision must immediately terminate if the required technology is not available and operating. [20 CSR 2220-2.710(2)(A)]

Examples of Supervision Allowed by 20 CSR 2220-2.710:

- A pharmacist is running late to open the pharmacy but is able to communicate with pharmacy

technicians/intern pharmacists and monitor delegated tasks using technology that complies with 20 CSR 2220-2.710. ** The technicians/intern pharmacists are not preparing, filling or dispensing medication.

Examples of Supervision **Not** Allowed By 20 CSR 2220-2.710

- The staff pharmacist is running late and the pharmacist-in-charge has authorized pharmacy staff to dispense prescriptions in the will-call bin that were previously verified by a pharmacist. Remote supervision of this activity is not allowed. Pharmacy technicians/intern pharmacists cannot compound, prepare, dispense or provide medication unless a pharmacist is physically present in the dispensing area.
- A Missouri licensed pharmacist is not at the pharmacy but is using video and audio technology to supervise intern pharmacists and pharmacy technicians administering vaccines. A pharmacist must be physically present on-site and directly supervising if an intern pharmacist or qualified pharmacy technician is administering medicine/vaccines. Remote supervision is not allowed.

****See D.16* for additional guidance for technology assisted supervision at Class R Remote Dispensing sites.*

The following chart contains a general summary of Missouri's technology-assisted supervision allowances:

Pharmacy Technician/Intern Pharmacist Technology Assisted Supervision Requirements

(Licensees should review the rules and applicable Practice Guide sections for all compliance requirements; Additional restrictions/requirements apply that are not listed below.)

	Technician/intern pharmacist assisting at a Missouri Licensed Pharmacy (20 CSR 2220-2.010) *Tech is on-site & RPh is off-site/not available	Remote Data Entry Site (20 CSR 2220-2.725)	Off-Site Non-Dispensing Activities (20 CSR 2220-6.055)	Class R Remote Dispensing Pharmacy Sites (§ 338.215)
Technology assisted supervision allowed?	✔ *Remote/technology-assisted supervision not allowed if technicians/intern pharmacists are compounding, preparing or dispensing medication	✔	✔	✔
Real-time audio communication mechanism between pharmacist & technician/ intern pharmacist?	* "Sufficient" Communication method required; Real-time communication method recommended but not required	✔	✔	✔
Video technology?	* If needed to verify and ensure activities are safely and properly performed.	* If needed to verify and ensure activities are safely and properly performed.	* If needed to verify and ensure activities are safely and properly performed.	✔
Completion of employer training?	✔	✔	✔	✔
Initial & annual competency assessment?	✔ (required if technician/ intern pharmacist supervised via technology)	✔	✔	✔

C.4 PRESCRIPTIVE AUTHORITY

Section 338.010.1 grants pharmacists authority to prescribe a prescription or over-the-counter "nicotine replacement therapy product." [See C.10 for additional information]. While not full prescriptive authority, pharmacists may also:

- Dispense naloxone hydrochloride or naltrexone hydrochloride without a prescription pursuant to a statewide standing order or by protocol with a Missouri licensed physician (See C.11)
- Dispense human immunodeficiency virus post-exposure prophylaxis (HIV PEP) pursuant to a protocol with a Missouri licensed physician (see C.12/Rules not currently effective)
- Initiate or modify medication therapy or devices with a certificate of medication therapeutic plan authority and medication therapy services protocol. This includes selecting a new or different medication or discontinuing medication (See Section N for requirements),
- Administer vaccines under protocol with a Missouri licensed physician (see Section M), and
- Dispense an emergency supply of non-controlled medication if the pharmacist is unable to obtain refill authorization from the prescriber. (See H.17)

C.5 NON-DISPENSING ACTIVITIES OUTSIDE OF A PHARMACY

Generally, the practice of pharmacy may only be performed on the premises of a Missouri-licensed pharmacy. However, 20 CSR 2220-6.055 allows a Missouri-licensed pharmacist to perform the following non-dispensing activities outside of a licensed pharmacy:

1) *Patient counseling/education*
2) *Obtaining patient history/information*
3) *Reviewing patient records/medical histories*
4) *Patient assessment/evaluation, as authorized byMissouri law*
5) *Medication therapy management*
6) *Billing and insurance claim submissions/ review*
7) *Drug utilization review*
8) *Assessing payor eligibility/coverage*
9) *Pharmacy compliance audits/evaluations*
10) *Administering drugs, vaccines, or biologicals, asauthorized by law and the rules of the Board*
11) *Peer review/peer consultations*
12) *Reviewing, selecting, and developing formularies or plan/practice guidelines*
13) *Reviewing compliance with benefit guidelines*
14) *Managing inventory, including purchasing and ordering*
15) *Managing/reviewing information systems*
16) *Patient medication review*
17) *Consulting with other health care professionals*
18) *Patient referrals*
19) *Medication therapy management*
20) *Prescription order entry/review, provided that a pharmacist may only accept a written prescription on the premises of a Missouri licensed pharmacy.***
21) *Electronic final product verification (a pharmacist must be present at the pharmacy whenever technicians or intern pharmacists are compounding, preparing or dispensing medication, except as otherwise provided by law)*

Adequate security and supervision must be maintained at off-site locations to ensure and maintain confidentiality of patient information/records at all times. Pharmacists operating under 20 CSR 2220-6.055 are prohibited from meeting with patients in the pharmacist's residence or living quarters.

*** Pharmacists may take a verbal order or call the prescriber to clarify a prescription/medication order outside of a pharmacy. However, hard copy and faxed prescriptions/medication orders can only be accepted at a licensed pharmacy location.*

Pharmacy technicians and intern pharmacists may assist a pharmacist with non-dispensing activities outside of the pharmacy if the technician/intern pharmacist is under the direct supervision of a Missouri licensed pharmacist who is "readily and immediately available," as required by 20 CSR 2220-2.010 and 20 CSR 2220-2.710 (see C.2 Staff Supervision).

- The supervising pharmacist must either be physically present at the offsite location when supervising, or supervise pharmacy staff via technology that complies with 20 CSR 2220-2.710. (See C.3 for additional technology supervision requirements). The required technology must allow the supervising pharmacist to properly monitor the pharmacy technician's/intern pharmacist's activities at all times. [20 CSR 2220-6.055(6)(C)].
- *Training:* Pharmacy technicians and intern pharmacists assisting at an off-site location must have completed employer approved training in the activities performed and must have an initial and an annual documented competency assessment. The form and content of the required training and competency assessment is in the pharmacy's discretion. Proof of training compliance must be maintained in the pharmacy's records. Additional employer training/competency assessment is not required for technicians/intern pharmacists only assisting with immunizations off-site (see Section O and Section P for technician/intern pharmacist vaccine/administration training requirements).
- The supervising pharmacist must be available to respond to pharmacy technician/intern pharmacist questions at all times the technician/intern pharmacist is assisting at a non-pharmacy location. A sufficient HIPAA compliant mechanism must be in place to allow real-time communication between the pharmacist and pharmacy technician/intern pharmacist when needed (e.g., phone, audio/video technology) *Note: The real time communication requirement is an additional requirement for technicians/intern pharmacists assisting outside of a licensed pharmacy.*

Pharmacy technicians/intern pharmacists cannot receive or accept a prescription outside of a Missouri licensed pharmacy (written or verbal). This restriction is mandated by § 338.095.5 and cannot be waived by the Board.

- 20 CSR 2220-6.055 does not apply to delivery drivers delivering filled prescriptions/medication orders who are not performing pharmacy technician activities.
- Pharmacy technicians routinely engaged in remote data entry at an off-site location without a pharmacist present would be required to comply with remote data entry requirements (see H.3 Remote Data Entry).

C.6 TELE-PHARMACY

Missouri law doesn't define "tele-pharmacy" and use of the term may vary depending on the practice setting. However, 20 CSR 2220-6.055 allows pharmacists to electronically or remotely provide a variety of non-dispensing pharmacy services from within or outside of a pharmacy, as detailed in section C.5. Additionally, rule 20 CSR 2220-2.011 allows pharmacists to remotely verify prescriptions/medication orders using a qualifying electronic final verification system that complies with the rule (see H.5). Remote pharmacist supervision/final product verification is also authorized for Class R Remote Dispensing Site pharmacies under § 338.215, RSMo. (see D.16). Licensees should thoroughly review § 338.215 and the above rules to ensure compliance (see C.3 for remote supervision of pharmacy staff via technology).

C.7 CONSULTING ACTIVITIES/CLASS-I PHARMACIES

A Missouri licensed pharmacist may provide consulting services without a Missouri pharmacy permit, as a non-dispensing activity authorized by 20 CSR 2220-6.055. Although the Board issues a Class-I Consultant pharmacy permit, a class-I permit is only required if:

- The pharmacist will be accepting prescriptions from patients at the location, or
- The pharmacist will be doing business under or using the name of "pharmacy", "apothecary" or "drug store" or any similar symbols, words or phrases are used in any form to advertise retail products or services. [§ 338.210; 338.260, 20 CSR 2220-6.055]

Patients are not allowed in a Class I pharmacy located within a residence. [20 CSR 2220-2.010(6)]

The Board is frequently asked if a pharmacist in another state can be used to perform DUR or prescription order review for a Missouri licensed pharmacy. Except as otherwise authorized by law, pharmacists not located in Missouri may provide pharmacy services for patients or pharmacies located in Missouri if:

- The individual is a Missouri licensed pharmacist, or
- The pharmacist is working for a Missouri licensed pharmacy. [20 CSR 2220-2.010(1)(F)]

C.8 RPh PROTOCOLS/STANDING ORDERS

Protocols: Missouri law currently authorizes the following activities/dispensing under protocol with a Missouri licensed physician:

- Immunizing without a prescription (See Section M)
- Medication Therapy Services (See Section N)
- Prescribing HIV Post-Exposure Prophylaxis without a prescription (See C.12 ****Rules not currently effective*)
- Dispense naloxone hydrochloride or naltrexone hydrochloride without a prescription (See C.11)

Protocol requirements will differ based on the specific activity (see the above sections for additional compliance information).

Standing Orders: Missouri law allows pharmacists to dispense the following without a prescription pursuant to a statewide standing order issued by the Missouri Department of Health and Senior Services (DHSS):

- Naloxone hydrochloride (see Section C.11)
- Naltrexone hydrochloride (see Section C.11; **Standing order has not been issued)*
- Drug deactivation and disposal products (effective December 23, 2021).

DHSS standing orders may have been issued or modified/rescinded since the publication of this Practice Guide; Visit the Board's website for current DHSS standing orders at https://pr.mo.gov/pharmacists-standing-orders.asp

C.9 PATIENT MEDICAL TESTING

The federal Centers for Medicare & Medicaid Services (CMS) regulates all non-research laboratory testing on humans pursuant to the Clinical Laboratory Improvement Amendments of 1988. CLIA regulates three categories of testing: (1) high complexity testing, (2) moderate complexity testing, and (3) CLIA waived testing that does not pose a significant risk of patient harm if the test is performed correctly.

A CLIA certificate is required for pharmacies providing diagnostic/non-CLIA waived testing; A CLIA waiver is required for pharmacies providing CLIA-waived testing. The Missouri Department of Health and Senior Services

(DHSS) administers the CLIA program in the state of Missouri. Information on applying for a CLIA certificate is available on DHSS' website at https://health.mo.gov/safety/clia/. The Missouri CLIA Program can also be contacted at: CLIA@health.mo.gov.

Can Missouri licensees perform CLIA testing? Missouri law does not specifically address pharmacies or pharmacists providing CLIA testing, including, CLIA waived testing. Absent statutory direction, licensees performing CLIA testing should consult with legal counsel to ensure compliance.

If CLIA testing is provided, testing services should comply with professional standards of practice and be consistent withthe pharmacist's education, training and experience. Pharmacists should be competent in the services performed and must comply with all applicable state/federal law. *Note: Pharmacists cannot diagnose under Missouri law.*

Additional federal CLIA-testing resources:

- CMS: How to Obtain a CLIA Certificate of Waiver
- CMS: Comparison of COVID-19 testing & testing requirements chart
- CDC: Test or Not to Test? Considerations for Waived Testing

C.10 NICOTINE REPLACEMENT THERAPY PRODUCTS

Section 338.010.1 grants pharmacists authority to prescribe a prescription or over-the-counter "nicotine replacement therapy product" which is defined as:

> *Any drug or product, regardless of whether it is available over-the-counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation. [§ 338.665]*

Pharmacists may independently prescribe an authorized NRT product; A physician protocol or collaborative practice agreement is not required. No additional pharmacist training, licensure or Board notification is required by § 338.665 or 20 CSR 2220-6.200. However, pharmacists must be competent to perform the services provided and must maintain ongoing/continued competency. [20 CSR 2220-6.200(2)]

Prior to prescribing, pharmacists must:

- Collect a patient/medical history that will allow the pharmacist to properly assess the patient and safely provide patient care; and
- Utilize screening procedures based on generally accepted clinical guidelines to identify appropriate patients for treatment. High-risk patients or patients with a contraindication must be referred to the patient's primary care provider or an appropriate healthcare provider, when deemed necessary or appropriate. [20 CSR 2220-6.200(3) (A)]

The Board has not approved or adopted a standard screening procedure. Instead, pharmacists should use their professional judgment to select screening procedures/criteria appropriate for your practice setting. The following resources may be helpful and include clinical screening guidelines from other state/federal entities:

(The resources below are provided for informational purposes only and are not endorsed or sponsored by the Board. Licensees should refer to the most current version of the resource listed; The publications may have been amended or updated since this document was published)

- Clinical Practice Guideline – Treating Tobacco Use and Dependence (U.S. Dept. of Health and Human Services, Public Health Services)
- Indian Health Services Pharmacist Tobacco Cessation Clinic Protocol
- APhA Promising Practices for Pharmacist Engagement in Tobacco Cessation Interventions

Screening procedures should be documented in the pharmacist's records; Proof of compliance will be requested on inspection.

Prescriptions: Prescriptions for NRT products must comply with 20 CSR 2220-2.018 and all other state/federal law. The prescribing pharmacist should be identified as the prescriber of record. NRT prescriptions may be provided directly to the patient or transmitted to another pharmacy for dispensing.

Patient Medical Records: Pharmacists must maintain an adequate and complete medical record for each patient that documents the care provided. At a minimum, the patient's medical record must include:

1. The patient's name, birthdate, address and telephone number
2. The date(s) the patient was seen
3. The patient's primary care provider (if provided)
4. Documentation of the required patient screening
5. Any pertinent medical or medication information/history
6. The name and dosage of any medication prescribed
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals. [20 CSR 2220-6.200(4)]

This list includes minimum requirements. Pharmacists should use their professional judgment to determine if additional medical information is needed or required.

Records: Patient medical records must be securely and confidentially maintained in compliance with applicable state and federal law. Medical records may be stored separately or with the pharmacy's prescription records, provided medical records must be individually retrievable for each patient. [20 CSR 2220-6.200(4)]

At a minimum, patient medical records must be maintained for five (5) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request. [20 CSR 2220-6.200(4)(B)]

Additional Tobacco Cessation Resources:

- CDC TIPS: (CDC smoking cessation resource site with clinical tips, recommendations and patient education materials)
- CDC Smoking & Tobacco Resource Page
- University of California- San Francisco Smoking Cessation Center

The Missouri Tobacco Quit Line provides free patient resources for Missouri citizens seeking to quit tobacco use,

including, free access to professional counselors 24-hours a day, 7-days a week. The toll-free Missouri Tobacco Quit Line can be reached at:

MISSOURI TOBACCO QUITLINE
1.800.QUIT.NOW (784.8669)

(Sponsored by the Missouri Department of Health and Senior Services)

C.11 NALOXONE/NALTREXONE

Missouri pharmacists may dispense/distribute naloxone HCL without a prescription either:

1. Under protocol with a Missouri licensed physician, or
2. Pursuant to a statewide standing order issued/approved by the Missouri Department of Health and Senior Services ("DHSS"), or
3. To a qualified first responder agency as defined by § 190.255, or
4. To any person/organization acting under a standing order issued by a healthcare professional who is authorized to prescribe an opioid antagonist [§ 195.206.3, § 338.205]

No additional Board or DHSS licensure, certification or training is required. However, pharmacists should educate themselves on proper naloxone use and administration before dispensing.

A variety of naloxone educational materials are available on the Board's website, including:

- The Opioid Overdose Prevention Toolkit published by the United States Substance Abuse and Mental Health Services Administration (SAHMSA), and
- An Opioid Safety and Naloxone Brochure for Missouri patients and caregivers. *(Complimentary copies can be requested by e-mailing MissouriBOP@pr.mo.gov or by contacting the Board office. Quantities may be limited).*

Naltrexone:

Effective August 28, 2022, § 195.206.3 authorizes a Missouri-licensed pharmacist to sell and dispense an "addiction mitigation medication" under physician protocol or under a statewide standing order issued by the Missouri DHSS. An "addiction mitigation medication" is defined as "naltrexone hydrochloride that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering." [§ 195.206.1(1)]

As of October 2022, DHSS has not issued a standing order for naltrexone hydrochloride and the Board has not issued a governing rule. In the interim, the Board recommends that physician protocols clearly delineate authorized activities and whether a naltrexone prescription can be created in the physician's name.

Pharmacists selling/dispensing an addiction mitigation medication under § 195.206.3 must be competent to perform the services provided in accordance with applicable standards of care and maintain ongoing competency. Pharmacists should maintain an adequate medical record for each patient that documents the care provided. At a minimum, the Board recommends maintaining the following records:

1. The patient's name, birthdate, address and telephone number
2. The date(s) the patient was seen
3. The patient's primary care provider (if provided)
4. Documentation of any patient screening/testing
5. Any pertinent medical or medication information/history

6. The name and dosage of any medication prescribed
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals.

This list includes the Board's minimum recommendations. Pharmacists should use their professional judgment to determine if additional medical information is needed or required.

C.12 HIV Post-Exposure Prophylaxis

Section 338.730, RSMo, authorizes pharmacists to dispense human immunodeficiency virus post-exposure prophylaxis (HIV PEP) without a prescription pursuant to a written protocol with a Missouri licensed physician. Rules must be jointly promulgated by the Board and the Missouri Board of Registration for the Healing Arts to implement § 338.730. The joint rule has been submitted for rulemaking and will likely be effective in 2023. *** Pharmacists may not dispense HIV PEP without a prescription until the joint rules are effective.*** Licensees should monitor the Board's website for additional updates.

C.13 EXPEDITED PARTNER THERAPY

Section 191.648, RSMo, authorizes a Missouri licensed physician to issue a prescription to treat chlamydia or gonorrhea for a partner of a patient with chlamydia or gonorrhea, even if the partner does not have an established physician-patient relationship with the physician ("expedited partner therapy"). The statute requires the Missouri Department of Health and Senior Services and the Missouri Division of Professional Registration to jointly promulgate rules to implement the expedited partner therapy allowance. Implementing rules are not currently effective; Licensees should monitor the Board's website for updates.

D.1 PHARMACY DEFINITION

No person or entity may open, establish, operate or maintain a pharmacy in the state of Missouri without a valid Missouri pharmacy permit. A pharmacy includes, but is not limited to, any place:

- Where the practice of pharmacy is offered or conducted or where the practice of pharmacy is provided by a pharmacist or someone acting under the pharmacist's supervision or authority;
- Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed, sold or offered for sale at retail;
- Where the words "pharmacist", "apothecary", "pharmacy", "drugstore", "drugs" or any other similar symbols, words or phrases are used in any form to advertise retail products or services; or
- Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy, or to comply with any relevant laws regulating the acquisition, possession, handling, transfer,sale or destruction of drugs, chemicals, medicines, prescriptions or poisons. [§ 338.210; 338.260]

See C.5 for authorized non-dispensing activities without a pharmacy permit.

D.2 PHARMACY CLASSIFICATIONS

The Board issues the following classes of pharmacy permits [§ 338.220, 20 CSR 2220-2.020(9)]:

CLASS	DESCRIPTION
Class A (Community/Ambulatory)	Required to provide pharmacy services to the general public (e.g., retail).
Class B (Hospital Pharmacy)	A pharmacy owned, managed, or operated by a hospital as defined by § 197.020 or a hospital clinic or facility under common control, management or ownership ofthe same hospital or hospital system. [§ 338.220.6]. ** Licensure is not required for hospital pharmacies operating under the jurisdiction of the Missouri Department ofHealth and Senior Services. See D.10 for additional information.*
Class C (Long-Term Care)	Required for pharmacies dispensing drugs/devices to patients residing in a long-term care facility which would include a nursing home, retirement facility, mental care facility or any other facility that provides extended health care to resident patients. *See Section Q*.
Class D (Non-SterileCompounding)	Required for pharmacies providing non-sterile compounding as defined by 20 CSR 2220-2.400(3), in batch quantities using bulk active ingredients. [See 20 CSR 2220-2.400].
Class E (Radiopharmaceutical)	Required for pharmacies providing radiopharmaceutical services and where radiopharmaceuticals and chemicals classified as legend drugs are prepared, compounded, dispensed, stored, sold or used for nuclear medicine procedures. [See 20 CSR 2220-2.500 and section D.11].
Class F (Renal Dialysis)	Required for pharmacies dispensing renal dialysis solutions and other drugs/devices associated with dialysis care. Renal dialysis pharmacies may not be open to the general public and may only dispense renal dialysis solutions and renal dialysis associated drugs, supplies or devices. [See 20 CSR 2220-2.600].

CLASS	DESCRIPTION
Class G (Medical Gas)	Required for pharmacies providing oxygen and other prescription gases by prescription for therapeutic use.
Class H (Sterile Product Compounding)	Required for sterile compounding pharmacies, as defined by 20 CSR 2220-2.200.
Class I (Consultant)	Available for locations where the practice of pharmacy is conducted but is not used for procuring, storing, possessing or owning drugs.
Class J (Shared Service)	Required for pharmacies engaged in shared serves with/for another pharmacy such as, filling/refilling medication, central fill services, drug utilization review or therapeutic interventions. *See D.12* [20 CSR 2220-2.650].
Class K (Internet)	Required for pharmacies receiving, reviewing, preparing, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for new prescriptions originated from the internet for more than 90% of the pharmacy's total new prescription volume on any day. *See the Ryan Haight Act for additional federal requirements.*
Class L (Veterinary)	Available for entities selling, dispensing, or filling prescription drugs for animal use who would like to utilize the exemptions in 20 CSR 2220-2.675. *Note: Class-A pharmacies do not need an additional Class L permit.*
Class M: Specialty (Bleeding Disorder)	Required for pharmacies providing blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders. *See 20 CSR 2220-6.100.*
Class N: Automated Dispensing System (Health Care Facility)	Required for pharmacies operating automated/mechanical systems in a healthcare facility to store, package or dispense medication. *See 20 CSR 2220-2.900.*
Class O: Automated Dispensing System (Ambulatory)	Required for pharmacies operating automated/mechanical systems in an ambulatory setting to store, package or dispense medication. *See 20 CSR 2220-2.900.*
Class P: Practitioner Office/Clinic	Available for pharmacies operating in a practitioner's office/clinic and providing pharmacy services solely for patients of the practitioner(s). The Board has not promulgated separate rules for Class P pharmacies. In the interim, Class P pharmacies must comply with all provisions applicable to Class A pharmacies pending additional rulemaking. *** A pharmacy permit is not required for practitioner office dispensing to their own patients.*
Class Q: Charitable Pharmacy	A Missouri site that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients. Class Q pharmacies may only provide services to or for qualified indigent patients. [See D.15/20 CSR 2220-2.685 for definitions/requirements]
Class R (Remote Dispensing Site Pharmacy)	Any location in this state where the practice of pharmacy occurs and that is licensed as a pharmacy to dispense prescription drugs and is staffed by one or more qualified pharmacy technicians, or intern pharmacists, whose activities are supervised by a pharmacist at a supervising pharmacy through a continuous real-time audio and video link. Does not include prescriber office dispensing or an automated device [§338.215; 20 CSR 2220-2.680]

Pharmacies may only engage in the pharmacy activities allowed for the class(es) reflected on the pharmacy's permit. A Change of Classification Application must be filed with the Board to add or delete a class. Pharmacies may not function under an added class until the Board has issued a new permit reflecting the new classification.

Pharmacies must comply with all regulations governing each class listed on the pharmacy's permit even if they are not actually performing the activities. For example, a Class H Sterile Product pharmacy must comply with the Board's sterile compounding rules even if the pharmacy isn't currently providing sterile compounding services.

D.3 LICENSE REQUIREMENTS

Applicants for a resident or non-resident pharmacy permit must file an application with the Board and meet the following requirements:

- The pharmacy must designate and be under the supervision of a "pharmacist-in-charge";
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary, and orderly manner;
- In-state pharmacies must pass a Board inspection prior to licensure (see D. 4 for non-resident pharmacies); and
- Proposed/current operations must comply with Chapter 338 and all applicable state/federal law. [20 CSR 2220- 2.010(1)(C) – (F), 20 CSR 2220-2.020]

Pharmacies may be owned by unlicensed persons/entities. However, the practice of pharmacy may only be conducted by licensed pharmacists. A pharmacy permit is not required for practitioner office dispensing to their own patients.

D.4 NON-RESIDENT PHARMACIES

Pharmacies located outside of Missouri may not ship, mail or deliver a filled prescription/medication order into Missouri without first obtaining a Missouri pharmacy permit [20 CSR 2220-2.025]. To be eligible for licensure, a non-resident pharmacy must:

- Be located in the United States or a U.S. territory,
- Have a current and active pharmacy license in the state/territory where the non-resident pharmacy is physically located,
- Designate a pharmacist-in-charge who is either a Missouri licensed pharmacist or who holds an active pharmacist license in the non-resident pharmacy's licensing state/territory, and
- Submit a copy of the pharmacy's most recent state inspection. For sterile compounding applicants, the inspection must have occurred within the last eighteen (18) months. For all other pharmacy applicants, the inspection must have occurred within the last twenty-four (24) months.** [20 CSR 2220-2.025]

A non-resident pharmacy permit cannot be renewed if the applicant does not hold a valid pharmacy license in their home state. [§ 338.270]

*** If a state inspection is unavailable, 20 CSR 2220-2.025 provides a non-resident pharmacy applicant may also submit an inspection from the Verified Pharmacy Program (VPP) operated by the National Association of State Boards of Pharmacy. Alternatively, the Board can accept an equivalent third-party inspection by an entity approved by the Board or by a Board inspector (pending availability/resources). Contact the Board office for approval of an inspection entity other than a state agency or NABP.*

D.5 PHARMACIST-IN-CHARGE

All licensed pharmacies must designate a licensed pharmacist to serve as "pharmacist-in-charge" (PIC). [20 CSR 2220- 2.010(1)(M)]. For Missouri resident pharmacies, the PIC must hold a Missouri pharmacist license. For non-resident pharmacies, the PIC must be licensed in Missouri or in the state where the pharmacy is located.

The PIC is personally responsible for supervising pharmacy staff and ensuring that pharmacy operations and clinical activities comply with state/federal law, in conjunction with the permit holder. The PIC must be involved in and engaged with pharmacy operations and monitoring pharmacy compliance on a regular basis. Missouri law does not mandate minimum PIC work requirements (e.g., mandatory hours per day/week). Instead, the PIC must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance [20 CSR 2220-2.090(1)(B)].

PICs should collaborate with permit holders to identify how often the PIC needs to be physically present at the pharmacy to adequately supervise the pharmacy/staff. The Board recommends that PICs/permit holders consider:

1. The nature and volume of pharmacy activities, including, peak pharmacy periods (e.g., flu season)
2. Available staffing
3. Clinical services provided
4. Staff training, education, and experience, and
5. Pharmacy inspection and compliance history (e.g., previous inspection reports/compliance notices and any prior disciplinary orders).

A pharmacist may serve as PIC for more than one pharmacy. However, the PIC must be regularly engaged in/involved with pharmacy operations at each pharmacy, and must be physically present at each pharmacy for a sufficient amount of time to supervise pharmacy activities/compliance, as required by 20 CSR 2220-2.090.

To ensure appropriate PIC supervision and involvement, 20 CSR 2220-2.090 also includes the following requirements:

- Permit holders must provide the PIC ***designated time*** on a ***regular basis*** to review pharmacy compliance while the PIC is not engaged in dispensing medication or providing patient services. [20 CSR 2220-2.090(1)(B)] The frequency and length of the required PIC designated review time is in the permit holder's discretion. The PIC and permit holder should work collaboratively to identify an appropriate timeframe; Proof of compliance will be requested during an inspection.
- Permit holders must establish policies and procedures for regularly reviewing staffing and resource needs with the PIC, including, policies and procedures for requesting additional staff or staffing modifications. The mode/method of collaboration is in the permit holder's discretion but should provide the PIC a meaningful opportunity to discuss staffing concerns/needs.
- Permit holders must consult with the PIC and give the PIC an opportunity to provide input prior to

implementing any pharmacy policy, procedure, system, or practice that will modify or expand the delivery of pharmacy services (e.g., expanding clinical services or staffing reductions/changes that may impact pharmacy operations). Once again, the manner and method of gathering PIC input is in the permit holder's discretion, however, the PIC should have a meaningful opportunity to provide feedback in advance.

- PICs must have authority to temporarily suspend or restrict pharmacy operations or activity if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction of approval from the permit holder. A clear and documented permit holder-PIC communication and action plan is key and will limit pharmacy interruptions.

PICs should carefully review 20 CSR 2220-2.090 prior to assuming PIC responsibilities. Do not agree to serve as PIC if you cannot adequately supervise and monitor the pharmacy.

PIC CHANGES:

In the event of a PIC change, the pharmacy may not continue operations until a new PIC has been designated (*see below for interim supervising pharmacists*).

- The new PIC may begin serving immediately after designation. However, the permit holder must submit a completed Pharmacist-In-Charge Change Application to the Board within fifteen (15) calendar days to officially complete the change. [20 CSR 2220-2.010(1)(M)1.]. Pharmacies should keep a copy of the application in the pharmacy's records and document the mailing date to show compliance.
- A controlled substance inventory must be taken at or immediately prior to the PIC change that includes all Schedule II through V controlled substances, including, Schedule V pseudoephedrine containing over-the-counter products. [20 CSR 2220-2.010(1)(M)1.] Documentation of the inventory must be maintained in the pharmacy's records. To ensure accuracy, the Board recommends jointly conducting the inventory with both the former and new PIC, if possible.
- Extended Leave: If a PIC will be on extended leave (e.g., vacation, maternity leave), the PIC and permit holder should review the pharmacy's operations to determine if a new PIC should be named. If a new PIC is named, an official Pharmacist-In-Charge Change application must be filed. A second Pharmacist-In-Charge Change application must be filed if/when the previous PIC resumes PIC duties. Both PIC changes would require a separate controlled substance inventory.

Licensees have indicated finding a new PIC may take additional time and expressed concerns with adversely impacting patients if the pharmacy is forced to unexpectedly close due to a PIC vacancy (death, illness, other emergency). In response, 20 CSR 2220-2.010 was amended in 2022 to allow pharmacies to appoint an interim supervising pharmacist for up to thirty (30) days, if a new PIC cannot be immediately designated despite reasonable diligence. [20 CSR 2220-2.010(1)(M)2.]

a. For Missouri resident pharmacies, the Interim Supervising Pharmacists must hold a current and active Missouri pharmacist license. For non-resident pharmacies, the Interim Supervising Pharmacist must be licensed as a pharmacist in the state where the pharmacy is located.
b. Written notification of an interim supervising pharmacist designation must be immediately e-mailed to the Board office at: pharmacy@pr.mo.gov or faxed to the Board office at: (573) 526-3464. Additionally, the interim supervising pharmacist must complete an Interim Supervising Pharmacist Designation form agreeing to be responsible for pharmacy compliance while serving as the interim supervising pharmacist. Forms are available on the Board's website; No fees are required.

c. A documented controlled substance inventory must be taken when the interim supervising pharmacist is designated. The inventory must be retained in the pharmacy's records for two (2) years.
d. An interim supervising pharmacist may only serve for thirty (30) days. An official Change of Pharmacist-in-Charge application must be submitted when a permanent PIC is designated. An official PIC must be officially designated with the Board after the thirty (30) day period; A new Interim Supervising Pharmacist cannot be named. [20 CSR 2220-2.010(1)(M)2.]

An interim supervising pharmacist should only be appointed if the pharmacy cannot find a PIC despite reasonable diligence. Pharmacies should exercise good faith and should not use the interim supervising pharmacist allowance as an alternative to advance personnel planning.

- The Board's website includes several compliance resources that can be helpful to PICs including, a Pharmacy Self-Assessment Guide that can be used to assess the pharmacy's compliance status before an inspection. A "Compliance Tips for the Pharmacist-In-Charge" video is also available online at: https://pr.mo.gov/pharmacists-publications-resources.asp#videos
- New PICs: The Board recommends that new PICS review the pharmacy's prior compliance history, including, previous inspection reports/compliance notices and any prior disciplinary orders. Make sure violations have been addressed and corrected. Contact your inspector if you have questions about your previous inspections (Inspector contact information is available on the Board's website). Newly designated PICs should also sign up for the Board's e-alerts.

D.6 CHANGE OF OWNERSHIP

Pharmacy permits are issued for a named permit holder and are not transferable. Accordingly, a permit becomes void on the effective date of an ownership change and a new pharmacy permit is required for the new owners. [20 CSR 2220- 2.020(3)].

- *Sole Proprietors:* A pharmacy owned by a sole proprietor will be deemed to have changed ownership if: 1) the proprietor enters into a partnership with another individual or business entity, or 2) the proprietor dies. [20 CSR 2220-2.020(3)]
- *Corporations, LLCs, LLPs*: A new pharmacy permit is required if a corporation, limited liability partnership ("LLP"), or limited liability company ("LLC") begins or transfers ownership of a pharmacy. A new permit is required regardless of the relationship between the previous and subsequent owners. [20 CSR 2220-2.020(3)]

A Change of Ownership application is not required if:

- The pharmacy is owned by a corporation and the owners of the stock change. However, individuals/entities must notify the Board in writing within thirty (30) days of acquiring more than twenty-five percent (25%) of a pharmacy's ownership, or;
- The members or partners of a LLP or LLC change, as long as the partnership or company is not dissolved by the change. Partner/member changes must be reported to the Board in writing within ten (10) days. [20 CSR 2220- 2.020(3)].

Once a completed Change of Ownership Permit Application has been filed, the Board may issue a temporary pharmacy permit to allow the new ownership to continue operating until a new permit is issued.

New or amended DEA/BNDD controlled substance registrations may also be required in the event of an ownership change.

D.7 CHANGE OF LOCATION/REMODELING

Pharmacy permits are only valid for the address identified on the permit. A Pharmacy Location Change application must be filed with the Board before the pharmacy moves to a new location (an inspection is required for in-state pharmacies). [20 CSR 2220-2.020(4)]. If approved, the Board will issue a permit for the new location with the previous permit number. Licensees may not begin operating at the new location until a new license is issued. *Note: Permit holders should notify the Board in writing if the pharmacy's address changes but not the location. An amended permit will be issued without charge.*

Remodeling: Under rule 20 CSR 2220-2.020(4)(A), a pharmacy remodel includes:

- Any change in the storage conditions of Schedule II substances (this includes adding new storage or re locating existing storage),
- Any new connections to water/sewer resources (this includes relocating an existing sink), or
- Any changes in the overall physical security of drugs stored in the pharmacy (this can include acquiring additional pharmacy space).

A remodel is different from a change of location. A remodel involves modifications within an existing structure. A change of location is a move out of the current structure to a different structure. A Pharmacy Location Change application is not required for remodeling within an existing structure. However, a remodeling affidavit and project plans must be sent to the Board office or to your inspector no later than thirty (30) days before the remodeling begins. The required affidavit must include a description of the proposed changes and the projected completion date. [20 CSR 2220-2.020(4)(A)]. Official blueprints are not required- a diagram or rough blueprint sketches are acceptable.

Your inspector will notify you once the remodeling plans are approved or if additional information is needed. An inspection is not required for a remodel but may be conducted if deemed appropriate.

- *A move to a temporary structure outside of the existing building during a facility renovation is considered a change of location. A move back to the renovated area is considered a second location change. Both moves require a separate Location Change application (and an inspection for resident pharmacies).*
- *Class-B Hospital pharmacies must notify the Board if modifications constitute a remodel under 20 CSR 2220-2.020(4)'s definitions, even if the activity occurring within the licensed pharmacy is regulated by DHSS.*
- *Licensees should check with BNDD and the DEA to determine if a new or amended controlled substance registration is required for a change of location or remodel.*

D.8 DISASTERS/EMERGENCY RELOCATIONS

A pharmacy that is substantially unable to provide pharmacy services at their permitted location due to an emergency situation may file a Change of Location application with the board to provide pharmacy services at a temporary site. [20 CSR 2220-2.016(2)]. An emergency situation is defined as:

> *An emergency caused by a natural or man-made disaster that substantially prevents a Missouri licensed pharmacy from providing pharmacy services at the pharmacy's permitted location. [20 CSR 2220-2.016(1)(B)]*

Examples of a qualifying emergency situation would include, but may not be limited to, fires, floods, vandalism, or other weather events that prevent the pharmacy from substantially providing pharmacy services at the permitted location licensed with the Board for either a short or extended time period.

A Temporary Change of Location application must be submitted and approved prior to operating at the new location (no fee required). The temporary site must be located in Missouri and pass a Board inspection. Board staff will expedite inspection requests to the extent possible. [20 CSR 2220-2.016(2)(A)]

Approval of a Temporary Change of Location application will be based on the need, type, and scope of the emergency situation, as well as the pharmacy's ability to ensure proper security and compliance with state and federal drug laws at the temporary site. Unless otherwise approved by the board for good cause, temporary pharmacy permits are only valid for up to six (6) months (the Board may approve the location for less than six (6) months if deemed appropriate based on the emergency). [20 CSR 2220-2.016(2)(B)]

To avoid interruptions in patient care, the Board may waive designated facility or pharmacy operational requirements to allow a pharmacy to operate at a temporary location if requested. Waiver requests must be submitted to the Board in writing (at the Board's mailing address or e-mailed to: pharmacy@pr.mo.gov). Waiver requests must demonstrate/identify how the permit holder will maintain patient safety and ensure adequate security if the waiver is approved. [20 CSR 2220-2.016(2)(C)]

A second Change of Location application must be filed when the pharmacy is ready to return to their original application (no fee required). The pharmacy's original permitted location must pass a Board inspection prior to resuming pharmacy services at the original location. 20 CSR 2220-2.016(2)(D)] A Change of location application is also required if the pharmacy will be operating at a temporary location for more than the allowed six (6) months or will be permanently remaining at the approved temporary site. The temporary site will have to pass a full Board inspection and demonstrate compliance with all applicable pharmacy permit requirements.

Emergency Declarations/Disaster Areas

A Missouri licensed pharmacy located in Missouri may apply for an emergency temporary pharmacy permit to provide pharmacy services to Missouri patients impacted by an emergency declaration or patients located in a disaster area. [20 CSR 2220-2.016(3)] An official Temporary Pharmacy Permit application must be submitted with the applicable fee. Approval will be based on the need, type, and scope of emergency or disaster, as well as the pharmacy's ability to maintain proper security and comply with applicable state and federal law at the temporary site, including, section 338.240, RSMo. [20 CSR 2220-2.016(3)(C)] Pharmacies must be located in Missouri to be eligible for a temporary pharmacy permit to assist patients impacted by an emergency declaration or in a disaster area. Non-resident pharmacies are ineligible for a temporary pharmacy permit under 20 CSR 2220-2.016(3) **Note: A temporary pharmacy permit is different from a temporary change of location under 20 CSR 2220-2.016(2); Non-residents may still apply for a temporary change of location under 20 CSR 2220-2.016(2) to accommodate a pharmacy emergency that impacts the facility.*

Missouri pharmacies applying for an emergency temporary pharmacy permit must demonstrate that the temporary pharmacy is needed to ensure adequate pharmacy services are reasonably available for impacted patients. [20 CSR 2220-2.016(3)] The Board may not approve an emergency temporary pharmacy permit application if other pharmacies are available in or near the disaster area to meet patient needs.

Emergency temporary pharmacies will be considered part of the requesting pharmacy's permit ("home pharmacy") and not a separate/new pharmacy. [20 CSR 2220-2.016(3)] The home pharmacy is responsible

for ensuring compliance with all applicable state and federal law at an emergency temporary pharmacy. The pharmacist-in-charge (PIC) for the home pharmacy and temporary pharmacy must be the same.

The emergency temporary pharmacy permit will only be approved for the pharmacy classifications authorized on the home pharmacy's permit *prior to* the declared disaster or emergency declaration. [20 CSR 2220-2.016(3)(B)]. For example, a temporary pharmacy permit can only be approved for a Class C Long-Term Care permit if the home pharmacy was licensed as a Class C pharmacy prior to the applicable disaster/emergency declaration. New/different permit classifications cannot be added to an emergency temporary permit under 20 CSR 2220-2.016(3).

Temporary pharmacies must be available for a Board inspection. [20 CSR 2220-2.016(3)(D)] The Board may waive designated facility or pharmacy operational requirements for a temporary location on request to ensure patient access to pharmacy services. [20 CSR 2220-2.016(3)(E)] Waiver requests must be submitted in writing to the Board's mailing address or e-mailed to: pharmacy@pr.mo.gov. Waiver requests must demonstrate/identify how the permit holder will maintain patient safety and ensure adequate security if the waiver is approved. [20 CSR 2220-2.016(2)(C)]

Emergency temporary pharmacy permits are valid for thirty (30) days but may be renewed at the discretion of the Board. [20 CSR 2220-2.016(3)(F)] To renew, the home pharmacy must file a written request with the Board and demonstrate that continuation is needed to protect the public health and ensure access to pharmacy services. Temporary pharmacies must terminate services on the expiration date approved by the Board, or within five (5) days after the disaster area designation or emergency declaration is withdrawn or terminated, whichever is earlier. [20 CSR 2220-2.016(3)(G)]

Records must be maintained as required by Chapter 338, RSMo, and the rules of the Board. Required records must be maintained at the home pharmacy after the temporary pharmacy permit closes, and must be available for inspection or copying by the Board or the Board's authorized designee.

D.9 TERMINATING BUSINESS

Prior to terminating business, the PIC and the permit holder should ensure proper arrangements have been made for all inventory and pharmacy records. An Out-of-Business Notification Form must be filed with the Board within fifteen (15) days after the permit holder stops operating and the pharmacy's permit must be returned to the Board office. [20 CSR 2220-2.015(1)].

The closing pharmacy may transfer or dispose of medication in accordance with state and federal law. [20 CSR 2220- 2.015(2)]. A drug distributor license is not required for a one-time transfer of medication/devices if the pharmacy is terminating business. [20 CSR 2220-2.015(3)]. Pharmacies may not transfer misbranded, outdated or adulterated drugs, except for proper disposal.

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date and a copy of the inventory must be included in the records of each permit holder involved in the transfer. [20 CSR 2220- 2.015(2)(A)]. Controlled substances must be transferred via invoice or, if applicable, a DEA-222 form/CSOS.

Records: The closing pharmacy must designate a secure location where pharmacy records will be kept after the pharmacy is closed. The Board recommends informing patients of where/how to locate prescription records in the future. Records transferred to an unlicensed location must be retrievable within seven (7)

working days of a Board request. [20 CSR 2220-2.015(1)(C)]

D.10 CLASS-B HOSPITAL PHARMACY

A Class B Hospital Pharmacy is defined as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A "hospital clinic or facility" that is under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3)].

A Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required, however, a specialized permit classification would be required for any specialty pharmacy services under the Board's jurisdiction (e.g., Class D-Non- sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

Hospital clinics/facilities eligible for a Class-B permit may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers, or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (*this list is not exhaustive*). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board's jurisdiction. Applicants should consult with legal counsel to determine if a hospital clinic/facility is under "common control, management or ownership of the same hospital or hospital system." The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses. *(See C.5 for non-dispensing activities outside of a pharmacy).*

AUTHORIZED CLASS-B ACTIVITIES

Section 338.220, RSMo, grants two specific allowances to Class B Hospital pharmacies:

1. Class B Hospital pharmacies may dispense medication by prescription or by "medication order"; and
2. Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

DISPENSING BY PRESCRIPTION/MEDICATION ORDER

Section 338.220 authorizes Class-B pharmacies to dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements. A "medication order" is defined as an order for a legend drug or device that is:

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and
2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized

designee at a hospital or a "hospital clinic or facility" that is under the "common control, management or ownership of the same hospital or hospital system." [Section 338.165.1] A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

Missouri law is silent on a pharmacist's authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance. Medication orders must comply with all state/federal controlled substance requirements.

LABELING

Labeling must comply with § 338.059, RSMo (see H.7). The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059,'s labeling requirements if:

1. Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and
2. The medication/prescription container labeling is accurate and complies with DHSS' medication labeling requirements, and
3. The medication/prescription container is not "given to the patient for use/administration" offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

DISTRIBUTION WITHOUT A MISSOURI DRUG DISTRIBUTOR LICENSE

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a "hospital clinic or facility" for patient care or treatment without a Missouri drug distributor license *(see chart below)*. Once again, a "hospital clinic or facility" is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system. A Class-B Hospital pharmacy is required to keep a record of all distributions.

Although a Missouri drug distributor license is not required, pharmacies may still be required to register with the DEA as a controlled substances distributor under federal law if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year. *Note: Controlled substances may only be distributed to a BNDD/DEA controlled substance registrant via invoice or via CSOS/DEA-222 form (schedule IIs).*

A Class B pharmacy may not distribute compounded preparations to other entities or compound for office stock. However, an FDA registered drug manufacturer or a 503(b) drug outsourcing facility may provide compounded preparations for office use, provided the entity is also licensed as a Missouri drug distributor (for manufacturers) or a Missouri drug outsourcer (for 503(b) drug outsourcing facilities). *(See I.2 for additional information)*

HOSPITAL/CLASS-B DRUG DISTRIBUTION
Class-B Licensed Hospital Pharmacy: A drug distributor license is not required to: 1. Distribute to a hospital clinic or facility under common control, management or ownership 2. Receive returned medication that was distributed by the Class-B pharmacy to a hospital or clinic
Hospitals WITHOUT a Class-B Pharmacy License: A drug distributor license is not required to: 1. Distribute to another hospital (under same or different ownership) 2. Distribute to a healthcare entity under common control or ownership 3. Receive returned medication distributed by the hospital or healthcare entity under commoncontrol or ownership.
Hospital Owned Clinics/Other Entities: A drug distributor license is required to distribute a medication to any entity, including: 1. A hospital (under same or different ownership) 2. Another clinic or hospital entity (under same or different ownership) 3. A Class-B pharmacy or other pharmacy *This does not include returning medication received from a Class-B pharmacy or hospital; A drug distributor license is not required to return medication back to the entity that it was received from.

RECORD-KEEPING

Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. The Board has determined that Class-B pharmacies may maintain dispensing, distribution, and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board. *Note: Controlled substance records* must still *be separately maintained/retrievable as required by state/federal law.*

"TECHNICIAN-CHECK-TECHNICIAN"

The Board's rules do not currently allow technicians to check/verify the final product prepared or compounded by another technician (tech-check-tech) for pharmacy services under the Board's jurisdiction. DHSS has promulgated 19 CSR 30-20.100(2) which authorizes a pharmacy technician to authenticate medication selected by another pharmacy technician when a pharmacist is present, subject to conditions/restrictions identified in the rule (additional technician training requirements apply). DHSS' rule is applicable to hospital pharmacy services under DHSS' jurisdiction. Hospital pharmacies providing pharmacy services under the Board's jurisdiction must comply with Board rules. (See H.6 for allowed technician/intern pharmacist electronic final product verification for pharmacy services under the Board's jurisdiction).

DRUG REPACKAGING FOR HOSPITAL SYSTEM DISTRIBUTION

The Board has been asked to provide guidance on repackaging of non-sterile drugs by a hospital or Class-B pharmacy for distribution to a healthcare entity under the same common control or ownership as the hospital.* The following guidance on Board rules is being provided for informational purposes. This

guidance only applies to repackaging of non-sterile drugs for distribution to a healthcare entity that is under the same common control or ownership of the hospital*. This guidance does not address:

- Repackaging for use within the same hospital at which the repackaging occurs
- Repackaging of sterile products
- Repackaging of compounded preparations
- Repackaging occurring outside of the hospital premises or outside of a Class-B pharmacy
- Repackaging occurring outside of Missouri
- Distribution to a healthcare entity that is not under the same common control or ownership as the hospital

** A hospital is limited to hospitals as defined by Chapter 197, RSMo, or a hospital operated by the state.*

Facility Where Repackaging isOccurring	Board of Pharmacy Requirements
Class B pharmacy located within or outside of the hospital premises	• Comply with 20 CSR 2220-2.130 Drug Repackaging and § 338.059.2 labeling • No drug distributor license required per 20 CSR 2220-5.020.
Hospital with BOP drug distributor license only	• Comply with chapter 20 CSR 2220-5, including 20 CSR 2220-5.030(4) which provides: (4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for— (A) Packaging; (B) Record keeping; (C) Expiration dating; (D) Plant facilities; (E) Equipment; (F) Personnel; (G) Production and control procedures; (H) Containers; and (I) Testing
Hospital with no BOP license	• No Bd. of Pharmacy jurisdiction. • Does not require a drug distributor license per 20 CSR 2220-5.020. • DHSS would regulate this activity for hospitals under their jurisdiction.

Distribution by entities outside of a hospital premises or a Class-B pharmacy would require a Missouri pharmacy permit or drug distributor license at that location. Note: Hospitals/Licensees should contact DEA/BNDD for controlled substance requirements and should also consult FDA for registration requirements if distributing outside of their own-system.

D.11 CLASS-E RADIOPHARMACEUTICALS (NUCLEAR)

A Class-E Radiopharmaceuticals pharmacy permit is required for any location that provides radiopharmaceutical services and where radiopharmaceuticals and chemicals classified as legend drugs are prepared, compounded, dispensed, stored, sold or used for nuclear medicine procedures. [20 CSR 2220-2.500(3)] To be eligible for licensure, the applicant must hold a current Nuclear Regulatory Commission

(NRC) and/or an Agreement State radioactive materials license.*

A Class-E permit is not required for:

1. Nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed under the supervision of a licensed physician authorized by the NRC or Agreement State regulations.*
2. Clinical laboratories licensed by the NRC or an Agreement State to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, provided the laboratory is not engaged in the commercial sale or resale of radiopharmaceuticals. [20 CSR 2220-2.500(1)(H)]

Class-E pharmacies must be under the supervision of an authorized nuclear pharmacist who holds a Missouri pharmacist license and who:

- Is certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
- Has attained status as an authorized nuclear pharmacist or an authorized user of radioactive material as specified by the NRC or Agreement State Regulations. [20 CSR 2220-2.500(3)]

Class-E pharmacies preparing, compounding or repackaging sterile preparations must also have a Class-H Sterile Compounding permit. Class-E pharmacies are no longer required to have a Missouri Drug Distributor license to provide non-patient specific nuclear preparations for a prescriber's use, provided the Class-E pharmacy complies with 20 CSR 2220-2.500

*ATTENTION: *An "agreement state" is defined as any state that has entered into an agreement under subsection 247b of the Atomic Energy Act of 1954, in which the U.S. Nuclear Regulatory Commission has relinquished to the state the majority of its regulatory authority over source material, by-product and special nuclear material in quantities not sufficient to form a critical mass. Missouri is not an agreement state. [20 CSR 2220-2.500(1)(A)]*

Facility Requirements

Class-E pharmacies must have adequate space and equipment that is commensurate with the scope of services provided. Additionally, Class-E pharmacies must comply with:

- All applicable facility/equipment requirements of the NRC or an Agreement State, [20 CSR 2220-2.500(4)]
- 20 CSR 2220-2.400 governing sterile compounding, and
- All applicable provisions of 20 CSR 2220-2.200 (Compounding Standards of Practice).

At a minimum, Class-E pharmacies handling radiopharmaceuticals must have a:

1. Radiopharmaceutical nonsterile and sterile preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area. [20 CSR 2220-2.500(4)]

Additionally, radionuclide generators must be stored and operated in an ISO 8 or better classified area. Nuclear pharmacy restricted areas must be totally enclosed and lockable and must be secured to prevent unauthorized access. [20 CSR 2220-2.500(4)(A), (B)]

References

Class-E pharmacies must have a current copy of or electronic access to the following references:

- Statutes and rule governing the pharmacy's practice, including, but not limited to, Chapter 338 and Chapter 195, RSMo, 20 CSR 2220 and 19 CSR 30 governing controlled substances (if applicable), and
- NRC or Agreement state regulations governing the safe storage, handling and dispensing of radioactive materials, including, but not limited to, Title 10 and Title 18 of the United States Code of Federal Regulations. [20 CSR 2220- 2.500(6)]

Prescription/Contingency Prescription Drug Orders

Radiopharmaceuticals may only be dispensed pursuant to a prescription drug order or a contingency prescription drug order from a practitioner or facility authorized by the NRC or Agreement State to possess, use and administer radiopharmaceuticals or the practitioner's/facility's designated agent. [20 CSR 2220-2.500(5)(C)].

- A "prescription drug order" is defined as a prescription drug order for a specific patient for a diagnostic or therapeutic purpose. [20 CSR 2220-2.500(1)(1)(L)]
- A "contingency prescription drug order" is defined as a radioactive prescription drug order issued for contingency material for a diagnostic purpose. [20 CSR 2220-2.500(1)(1)(E)]

Prescription drug orders/contingency prescription drug orders may only be taken by an authorized nuclear pharmacist or by an intern pharmacist or authorized nuclear pharmacy technician who is under the supervision of an authorized nuclear pharmacist (see below for verbal therapeutic prescription drug orders). [20 CSR 2220-2.500(5)(C)] An "authorized nuclear pharmacy technician" is defined as a person who has successfully completed:

- A nuclear pharmacy technician training program provided by an accredited college program,
- A program that meets the American Pharmacist's Association's (APhA) Guidelines for Nuclear Pharmacy Technician Training Programs, or
- An equivalent company sponsored program that meets APhA guidelines for nuclear pharmacy technician training. [20 CSR 2220-2.500(1)(I)]

Technician training programs do not have to be pre-approved by the Board, however, documentation of the required training should be maintained in the pharmacy's records.

Only an *authorized nuclear pharmacist* can receive verbal therapeutic prescription drug orders which are defined in 20 CSR 2220-2.500(1) as a radioactive prescription issued for a specific patient for a therapeutic purpose. [20 CSR 2220-2.500((5)(C)]. Verbal therapeutic prescription drug orders may not be received by an intern pharmacist or a pharmacy technician. [20 CSR 2220-2.500(5)(C)]

Prescription Records

Class-E pharmacies prescription records must include:

- The dispensing date and the calibration time of radiopharmaceuticals,
- The patient's name for therapeutic prescription drug orders and blood-containing products, and
- All information required by 20 CSR 2220-2.018. [20 CSR 2220-2.500(5)(C)]

Labeling

Radiopharmaceutical unit dose containers (the "pig") must be labeled with:

1. The name and address of the pharmacy,
2. The name and address of the authorized prescriber/facility where the prescription drug order/contingency prescription drug order is to be administered,
3. The dispensing date and a unique readily retrievable identifier,

4. The standard radiation symbol
5. The words "Caution Radioactive Material"
6. The name of the procedure (if known)
7. The name or generally recognized and accepted abbreviation of the radiopharmaceutical, radionuclide, and chemical form
8. The requested amount of radioactivity at the calibration date and time
9. The radiopharmaceutical beyond-use date
10. The quantity dispensed
11. If applicable, Molybdenum-99 content to *United States Pharmacopoeia* (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and
12. The patient's name or, in the absence of a patient name, "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order" or similar wording. If no patient name is used, the pharmacy must be able to retrieve the name of the patient from the authorized prescriber/facility within three (3) days if requested. However, the patient's name must appear on the label when the prescription is for a therapeutic or blood-containing radiopharmaceutical. [20 CSR 2220-2.500(5)(D)]

FDA approved radiopharmaceuticals are not subject to the above unit dose container labeling requirements or the radiometric measurement requirements of 20 CSR 2220-2.500 if the Class-E pharmacy does not process the radioactive drugs in any manner nor violate the original manufacturer product packaging/labeling. [20 CSR 2220-2.500(5)(D)]

The immediate inner container label of a radiopharmaceutical to be dispensed must be labeled with—

1. The standard radiation symbol
2. The words "Caution Radioactive Material"
3. The identity of the radiopharmaceutical
4. The unique, readily retrievable identifier of the radiopharmaceutical, and
5. The patient's name or, in the absence of a patient name, "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order" or similar wording. [20 CSR 2220-2.500(5)(E)]

Dispensing/Delivery

Radiopharmaceuticals may only be dispensed to:

- A practitioner or facility authorized by the NRC or an Agreement State to possess, use and administer such drug, or
- A person who is authorized to possess the drug in accordance with NRC/Agreement State regulations. [20 CSR 2220-2.500(5)(A)]

Radiopharmaceuticals may not be dispensed directly to a patient under any circumstances. [20 CSR 2220-2.500(5)(A)]

Class-E pharmacies must have on file a copy of the current radioactive materials license for each licensed facility requesting a radiopharmaceutical before the radioactive drug is dispensed to the facility. [20 CSR 2220-2.500(2)(C)]

Radiopharmaceuticals may only be delivered to the authorized address or locations listed in, or temporary job sites authorized by, the NRC/Agreement state license. The authorized physician ordering a radiopharmaceutical is recognized as the patient's authorized designee for delivery purposes under 20 CSR 2220-2.013. [20 CSR 2220-2.500(2)(C)]

A Class-E pharmacy may accept returns and waste as authorized by the NRC/Agreement State regulations. [20 CSR 2220-2.500(2)(F)]

**A Class-E pharmacy may distribute radionuclide elutions to other authorized users to meet a drug shortage. 20 CSR 2220-2.500(E)*

- The Board recognizes that visual verification of the final product as required by 20 CSR 2220-2.010 may not be safe or possible for some radiopharmaceuticals. Pharmacists should comply with 20 CSR 2220-2.500 (Nuclear Pharmacy) and take all appropriate and necessary steps to ensure accuracy of the final product and affixed unit dose label.

D.12 CLASS-J SHARED SERVICES

A Class-J Shared Services pharmacy permit is required if two (2) or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. [20 CSR2220-2.650(1)] Shared service activities that require a Class-J permit include, but are not limited to:

- *Receiving prescriptions/medication orders*
- *Prescription/order clarification or modification,*
- *Obtaining prescriber authorization,*
- *Data entry*
- *Compounding*
- *Dispensing*
- *Pharmacist verification*
- *Patient counseling,*
- *Patient profile maintenance*
- *Medication therapy services*
- *Medication administration*
- *Drug utilization review or*
- *Obtaining refill authorization.*

[20 CSR 2220-2.650(1)(A)]

To participate in a Class-J shared services arrangement both pharmacies must:

1. Have a separate Class-J pharmacy permit for each shared services location; and
2. Have the same owner or have a written contract outlining the shared services to be provided by each party and each party's responsibilities; and
3. Either share a common electronic database or have access to each pharmacy's prescription records and patient profiles/records, as needed to safely an properly perform the applicable shared services activities. [20 CSR 2220-2.650(1)(A)] *Note: The previous requirement for "real time, on-line" access to the patient's complete profile was modified, effective August 28, 2022. Joint access to patient/prescription records should now be available as needed to safely provide pharmacy services. Real time access may be best practice but is not required unless needed to safely provide patient care.*

Each pharmacy participating in a shared service arrangement must have a Class-J permit.

Pharmacies performing Class J services must maintain a detailed written description of authorized shared services that includes the name, address and Missouri pharmacy permit number for all pharmacies involved. The list must be current and should clearly identify authorized Class J services. Additionally, both Class J pharmacies must maintain a policy and procedure manual that includes:

1. Each pharmacy's duties and responsibilities, including, authorized Class-J duties;
2. A mechanism for tracking the prescription/medication order during each step in the process;

3. Security provisions for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring safe and appropriate prescription delivery in compliance with 20 CSR 2220-2.013, and
5. The identity of the pharmacy responsible for:
    a. Verifying prescription/medication order accuracy and validity
    b. Data entry verification
    c. Performing the drug utilization review required by 20 CSR 2220-2.195
    d. Final product verification; and
    e. Offering patient counseling and the pharmacy responsible for actually providing patient counseling as required by 20 CSR 2220-2.190/federal law (see below) [20 CSR 2220-2.650(1)(C)]

A pharmacy participating in Class-J Shared Services with a pharmacy that is not under common ownership must notify patients that their prescription or medication order may be filled or compounded by another pharmacy. Notification may be made verbally, electronically or in writing. [20 CSR 2220-2.650(3)]

Once filled, prescriptions or medication orders must be labeled in accordance with state and federal law. For purposes of § 338.059, either the name and address of the pharmacy responsible for offering patient counseling may be listed on the label or the name and address of the pharmacy responsible for dispensing to the patient, as designated by the pharmacies by contract and policies/procedures. [20 CSR 2220-2.650(1)(C)]

CLASS J EXEMPTIONS

Rule 20 CSR 2220-2.650 includes the following Class J license exemptions:

1. A Class-J permit is not required for pharmacists performing non-dispensing activities authorized by 20 CSR 2220-6.055 outside of a licensed pharmacy.
2. A Class J Shared Services permit is not required for pharmacies that have an arrangement to only provide initial dispensing services for a Class C Long-Term Care pharmacy, as allowed under 20 CSR 2220-2.120(4). For example, a Class J permit would not be required if a distant Class C Long Term Care pharmacy has a local pharmacy provide first dosing prescriptions to a local long-term care facility by transferring a partial amount of a prescription/order to the local pharmacy to cover the first dosing to the local pharmacy.
3. A Class-J permit is not required if a completed and labeled prescription is delivered from one Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional on the same premises as the pharmacy. [20 CSR 2220-2.650(2)] Administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion, or other means. [20 CSR 2220-2.650(2)] The receiving pharmacy must maintain documentation of the medication received, the providing pharmacy's name and address, the receipt date and the patient's name. The receiving pharmacy is also responsible for ensuring compliance with all applicable patient counseling requirements. [20 CSR 2220-2.650(2)(C)] **This exemption only applies if a completed and labeled prescription is delivered to the receiving pharmacy. [20 CSR 2220-2.650(2)(A)] If additional manipulation or compounding is required by the receiving pharmacy, a prescription/medication order is required and the prescription/medication order must be dispensed as the receiving pharmacy's own prescription/order.*
4. Effective November 30, 2022, a Class Q pharmacy receiving a completed and labeled prescription

from another pharmacy for an indigent patient is not considered to be shared services. [20 CSR 2220-2.685(9)] The receiving and providing pharmacy do not need a Class J permit for this activity (see D.15 Class Q Charitable Pharmacies for additional definitions/requirements).

QUALITY ASSURANCE PROGRAM

Class-J pharmacies must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems. [20 CSR 2220-2.650(1)(D)] Proof/documentation of your quality assurance program may be requested during an inspection. *(See D.17 for additional Quality Assurance guidance)*

- *Transferring prescription information between Class-J pharmacies for purposes of providing shared services is not considered a "prescription transfer" under 20 CSR 2220-2.120. However, other controlled substance laws may apply.*
- *Central-fill pharmacies dispensing controlled substances must comply with state and federal controlled substance laws.*

D.13 Class-L Veterinary Pharmacy

Rule 20 CSR 2220-2.675 establishes a Class-L veterinary pharmacy permit for pharmacies dispensing or providing drugs for animal use. [20 CSR 2220-2.675(1), (2)] Class-L pharmacies must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board. However, rule 20 CSR 2220-2.675 includes the following allowances/exemptions to accommodate Class-L dispensing:

1. Facility Standards: In lieu of a separate and distinct pharmacy area, Class-L services can be provided in the same space or area as other business operations/activities provided there is a defined area for storing legend drugs. The defined drug area must be clean and sanitary and legend drugs must be properly identified at all times. Additionally, medication must be stored within the appropriate temperature requirements as provided by the manufacturer or the latest edition of USP. Appropriate sewage disposal and a hot and cold water supply must be available. The water supply may be located outside of the pharmacy provided it is accessible to pharmacy staff *(This exemption does not apply if sterile or non-sterile compounding is performed)*. [20 CSR 2220-2.675(4)(F)]
2. Pharmacy Supervision: Class-L pharmacies may operate without a pharmacist physically present on-site, provided the PIC reviews the activities and records of the pharmacy's operations on a monthly basis. The date of the PIC monthly review must be documented in the pharmacy's records. This exemption does not apply and a pharmacist must be on site:
3. If controlled substances are stored at or provided by the pharmacy, or
4. Whenever compounding is performed (sterile or non-sterile). [20 CSR 2220-2.675(6)]
5. Dispensing Without A Pharmacist: Class-L pharmacies may accept, fill or dispense non-controlled legend drugs for animal use without a pharmacist present, provided the pharmacy has specific policies and procedures for operating without a pharmacist. [20 CSR 2220-2.675(6), (8)].
    - The PIC must review the prescription records for all legend medication provided without a pharmacist present each month. The PIC should be designated as the dispensing pharmacist for these prescriptions/orders unless verified by another pharmacist. The date of the required monthly PIC review must be documented in the pharmacy's records.
    - Patient/client counseling must be offered each time medication is dispensed/provided by a Class-L pharmacy, as required by 20 CSR 2220-2.190. If the pharmacist is not on-site, a written offer to counsel with a toll-free telephone number for contacting a pharmacist must be provided.
    - The pharmacy must have policies and procedures for reporting and handling dispensing errors. All dispensing errors must be reported to the PIC within twenty-four (24) hours.

- This exemption does not apply to controlled substances. Controlled substances must be verified by a pharmacist before dispensing. [20 CSR 2220-2.675(8)]

Class-L pharmacies may only dispense medication for animal use. An additional permit is required to dispense drugs for humans (e.g., Class-A). Class-A or Class-B pharmacies may dispense or provide legend drugs for both human and animal use under their Class-A/Class-B permit. An additional Class-L license is not required. However, Class-A or Class-B pharmacies would need an additional Class-L permit to use the Class-L exemptions (e.g., dispensing without a pharmacist).

Prescription Requirements: To be valid for dispensing, prescriptions for animal use must comply with § 338.056, RSMo, and § 338.196. Additionally, prescriptions must include:

1. The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;
2. The prescriber's name, if an oral prescription, or signature, if a written prescription;
3. Name, strength, and dosage form of the drug and directions for use;
4. The number of refills, when applicable;
5. The quantity prescribed in weight, volume, or number of units;
6. For controlled substances, the address of the prescriber, address of the patient, and the prescriber's DEA number. [20 CSR 2220-2.675(7)]

Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the Board (See Section K).

Section § 338.056 allows a pharmacist to substitute a generic product unless the prescriber prohibits substitution. 20 CSR 2220-2.675 needs to be amended to reflect the statutory language. In the interim, pharmacists dispensing medication for animal use may substitute a generic as authorized by § 338.056. Specific prescriber authorization to substitute is no longer statutorily required. (See H.11 for additional information)

Labeling: Legend medication for animal use must be labeled in accordance with § 338.059, RSMo. Labels must also include:

1. The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and
2. If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s). [20 CSR 2220-2.675(9)]

Compounding: Compounding can only be performed at a Class L pharmacy when a pharmacist is on site, and must comply with 20 CSR 2220-2.200 (non-sterile compounding) and 20 CSR 2220-2.400 (non-sterile compounding).

Controlled Substances: Class-L pharmacies must comply with all state/federal controlled substance laws, including, all security and prescription/order requirements. A pharmacist must be present and onsite during pharmacy operations if controlled substances are sold or provided. [20 CSR 2220-2.675(6)]

Policies and Procedures: Class-L pharmacies must maintain a policy and procedure manual that includes policies/ procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;
2. Accepting, dispensing or providing prescriptions in a pharmacist's absence, if applicable;
3. Drug storage and security;

4. Handling drug recalls;
5. Offering patient/client counseling;
6. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and
7. Reporting and handling dispensing errors, including, provisions for notifying the PIC of dispensing errors within the required twenty-four (24) hours. [20 CSR 2220-2.675(5)(C)]

The policy and procedure manual must be reviewed annually by the PIC and must be available on inspection or at the request of the Board.

D.14 Class-M Specialty Bleeding Disorder

A Class-M pharmacy permit is required for pharmacies providing or offering to provide blood-clotting factor or products to patients with bleeding disorders. Section 338.400, RSMo, and rule 20 CSR 2220-6.100 contain additional requirements for Class-M pharmacies that are:

- Dispensing blood-clotting factor concentrates, and
- Dispensing blood clotting products to "established patients" or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.

DISPENSING BLOOD-CLOTTING FACTOR CONCENTRATES

Class-M pharmacies dispensing blood-clotting factor concentrates to new or existing patients are required to complywith the following:

1. Barring extenuating circumstances, blood clotting factor concentrates must be dispensed within plus or minus ten percent (+/- 10%) of prescribed assays, or as otherwise authorized or directed by the prescriber. [20 CSR 2220-6.100(2)(E)].
2. Prescription Changes/Substitutions: Prescriptions for blood-clotting factor concentrates must be dispensed as written or as authorized by the prescriber. If the prescriber authorizes changing or substituting the blood-clotting factor concentrate originally prescribed, the patient/patient's designee must be notified and counseled regarding the change or substitution prior to dispensing via the patient's identified preferred contact method (see below). Counseling is mandatory unless refused by the patient/designee. [20 CSR 2220-6.100(2)(A)].
3. Automatic Refills: Unless previously authorized by the patient or the patient's designee, the patient must be contacted for authorization to dispense prior to shipping a refill of any blood-clotting product. Authorization may be given verbally or in writing and must be documented in the pharmacy's prescription records. The Board also recommends documenting the method/manner of authorization (e.g., written or verbal). [20 CSR 2220-6.100(2)(D)].
4. Delivery Requirements: If requested, blood-clotting factor concentrates must be shipped and delivered to the patient within two (2) business days for established patients in non-emergency situations, and three (3) business days for new patients. Non-emergencies include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used. [20 CSR 2220-6.100(2)(B)].
5. Pharmacy Contact: A toll free number for the pharmacy must be provided to patients to report problems with a delivery or product. The toll free number must be provided each time a prescription is dispensed (both new and refill). [20 CSR 2220-6.100(2)(C)].
6. Preferred Contact Method: The patient or the patient's designee must be asked to designate a

preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies. [20 CSR 2220-6.100(2)(C)]. The preferred contact method must be documented in the patient's prescription records.

7. Recall/Withdrawal Notifications: The patient and the prescriber must be notified by the pharmacy within twenty- four (24) hours after notification from the manufacturer or from any state/federal entity of a recall or withdrawal of any concentrate or ancillary infusion equipment/supplies. Notification is only required if the manufacturer or state/federal entity requires or recommends patient notification. The pharmacy is required to contact the prescriber to obtain a new prescription if necessary to dispense a substitute or alternative product. [20 CSR 2220-6.100(2)(F)1.].

If attempts to contact the patient via the preferred contact method are unsuccessful, notification must be mailed to the patient/patient's designee within the required twenty-four (24) hours or the next business day. The time, date, and method(s) of notification must be documented in the pharmacy's records and maintained for two (2) years from the date of recall or withdrawal. [20 CSR 2220-6.100(2)(F)].

Examples of currently known blood-clotting factor concentrates include:

Blood-Clotting Factor Concentrates**	Not a Blood-Clotting Factor Concentrate
· Recombinant Factor VII & Recombinant-activated Factor VIIa;	· Aminocaproic Acid;
· Recombinant Factor VIII & plasma-derived Factor VIII;	· Desmopressin Acetate;
· Recombinant Factor IX & plasma-derived Factor IX;	· Warfarin; and
· von Willebrand factor products;	· Heparin
· Bypass products for patients with inhibitors;	
· Prothrombin complex concentrates; and	
· Activated prothrombin complex concentrates.	

*** As currently approved by the FDA*

DISPENSING BLOOD-CLOTTING PRODUCTS

In addition to the requirements above, 20 CSR 2220-6.100(3) establishes requirements for Class-M pharmacies dispensing blood clotting products to "established patients" or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.

- An "**established patient**" is defined as a bleeding disorder patient that has been dispensed a legend blood-clottingproduct by the pharmacy on more than three (3) occasions in a single calendar year. [20 CSR 2220-6.100(1)(C)].
- A "**blood-clotting product**" is defined as:

  A medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products,

bypass products for patients with inhibitors, prothrombincomplex concentrates; and activated prothrombin complex concentrates. [§ 338.400(4)]

Gene therapy indicated for the treatment of bleeding disorders meets the definition of a blood-clotting product.

Except as otherwise provided by § 338.400, RSMo, a "blood clotting product" does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication. [20 CSR 2220-6.100(1)(B)].

- A "**bleeding disorder**" is defined as:

A medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand's disease,and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. [20 CSR 2220- 6.100(1)(A)]

A "bleeding disorder" does not include bleeding conditions secondary to another medical condition or diagnosis, except for acquired hemophilia. [20 CSR 2220-6.100(1)(A)].

Class-M pharmacies that are providing blood clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, have to comply with the following:

1) Board Notification: The pharmacy must notify the Board annually if the pharmacy intends on providing legend blood-clotting products to bleeding disorder patients. Notification must be made on or before January 31st of each year and should be submitted online at: pr.mo.gov/pharmacists-onlineservices.asp. [20 CSR 2220-6.100(3)(A)].
2) Pharmacist Availability: A pharmacist must be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products within the shipping/delivery time frames referenced below. [20 CSR 2220-6.100(3)(C)].
3) Supply Requirements: The pharmacy must identify, or make arrangements with, a supplier(s) who can provide all brands, assays and vial sizes of FDA approved blood-clotting products, including both, plasma and recombinant products. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Products do not have to be pre-purchased. Instead, the pharmacy must have an identified supplier if a product is needed. [20 CSR 2220-6.100(3)(B)].
4) Ancillary Supplies: Ancillary equipment and supplies required to infuse blood-clotting products intravenously must be available for purchase, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. Items must be restocked in a reasonable amount of time but in no event later than seven (7) calendar days. [20 CSR 2220-6.100(3)(H)].
5) Shipping/Delivery Requirements: If requested by an established patient, the pharmacy must provide for the shipment and delivery of blood-clotting products to the patient within two (2) business days after receiving a prescription or refill request. For new patients, shipment/delivery must be made within three (3) business days. In the event of an emergency, established patients must be provided access to blood-clotting products within twelve (12) hours after notification from the prescriber that an emergency supply is needed. Emergency requests must be documented in the pharmacy's records.

   If the pharmacy is waiting for action from a third-party payor prior to shipping/delivery (e.g.

authorization, certification, etc.), the patient must be notified that the prescription is ready and any alternate payment options must be explained. Notification must be made as soon as reasonably practicable but in no event later than the required delivery timeframe. Pharmacies may delay shipping/delivery until payment is confirmed.

6) Hazardous Waste: Hazardous waste disposal containers must be provided or available for purchase at the pharmacy (e.g.,- Sharps containers). [20 CSR 2220-6.100(3)(G)].

7) National Register: The pharmacy must register with the National Patient Notification System, or its successor, to receive recall notifications for all products included in the National Patient Notification System. Registration is free and may be completed online at www.patientnotificationsystem.org/. Contact information must be kept current and accurate. [20 CSR 2220-6.100(3)(K)].

8) Nursing Services: Contact information must be available for a nurse/nursing service with experience in providing infusion related nursing services or nursing services for bleeding disorder patients, if the nursing services are not provided by the pharmacy. [20 CSR 2220-6.100(3)(I)].

9) Insurance Information: If requested, the pharmacy must explain any known insurance copayments, deductibles, coinsurance payments or lifetime maximum insurance payment limits. [20 CSR 2220-6.100(3)(J)]. The Board recognizes that licensees may have limited access to or knowledge of benefit information. 20 CSR 2220-6.100(3)(J) provides the pharmacy may rely on information supplied by the patient's insurer.

10) Policy & Procedure Manual: The pharmacy must establish a written policy & procedure manual to ensure compliance with § 338.400 and 20 CSR 2220-6.100 that includes policies/procedures for: processing prescriptions, partial fills, providing/documenting recall notifications, emergency dispensing and cold chain management/packaging *(This list is not exhaustive; See 20 CSR 2220-6.100(4) for all policy and procedure requirements).* Policies and procedures must be reviewed annually. Documentation of the annual review must be maintained in the pharmacy's records. [20 CSR 2220-6.100(4)].

11) Pharmacist Training/Continuing Education: Pharmacists dispensing or filling blood-clotting factor concentrates for established patients or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients must have sufficient knowledge, experience and training to perform the duties assigned. Additionally, pharmacists engaged in counseling bleeding disorder patients must complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment/therapy or blood-clotting disorders or diseases each biennial renewal period. [20 CSR 2220-6.100(3)(D)]. The required CE hours can be used to meet the biennial pharmacist CE requirements.

D.15 Class Q Charitable Pharmacies

An organization qualified as a charitable organization under section 501(c)(3) of the Internal Revenue Code may apply for a Class Q Charitable Pharmacy which is defined as:

> *A site in Missouri that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients.*

[20 CSR 2220-2.685(1)(A)(B)]

Class Q Charitable pharmacies must be located in Missouri and may ***only*** provide services to or for qualified

indigent patients which are defined as:

> *A patient of a charitable pharmacy that has been screened and approved by a charitable organization and deemed not to have sufficient funds to obtain needed medication based on the charitable organization's pre-established criteria.*

Applicants are not eligible for a Class Q permit if they provide pharmacy services for or dispense to any other patients (e.g., the general public, other clinic/hospital patients, employees).

20 CSR 2220-2.685 includes provisions that would allow a qualified intern pharmacist or qualified pharmacy technician who has completed additional training/education to dispense non-controlled medication at a Class Q pharmacy when the pharmacist is absent, if the medication has been previously verified by a pharmacist and bar code technology is used to verify the right medication is being dispensed for the correct patient [20 CSR 2220-2.685(4); see 20 CSR 2220-2.685 for additional requirements). Additionally, a licensed physician, dentist, physician assistance or registered nurse may remove non-controlled medication from a Class Q pharmacy to provide or administer to patients on the premises, pursuant to a valid order (additional requirements apply). [20 CSR 2220-2.685(5)]

In addition to the above allowances, Class Q pharmacies may petition the Board to waive designated facility requirements that are not applicable to the Class Q pharmacy's operations. Waiver requests must demonstrate how the permit holder will maintain patient safety and ensure appropriate patient care and pharmacy security, if approved. [20 CSR 2220-2.685(3)]

To assist indigent patients, a Class Q pharmacy may accept and dispense donated medication if:

1. The medication is a non-controlled substance and is donated by a pharmacy, drug distributor, healthcare entity, or a healthcare provider who is licensed to prescribe;
2. The medication has not been previously dispensed to a patient and is donated in the original, sealed, and unopened manufacturer or unit of use packaging/container;
3. The medication is not adulterated, misbranded, expired, outdated, subject to a recall, or otherwise not appropriate for patient use. A pharmacist must visually inspect all donated medication prior to placing the medication in active inventory to ensure the medication complies with 20 CSR 2220-2.685;
4. The donating entity/healthcare provider attests in writing that the medication has been stored in accordance with manufacturer or United States Pharmacopeia requirements/guidelines and all applicable state and federal law;
5. The Class Q pharmacy maintains a record of donated medication that identifies the medication received, the donating entity/healthcare provider, the date received, and the medication's quantity, strength, lot number, dosage form, and expiration date; and
6. The parties comply with all applicable law. [20 CSR 2220-2.685(6)]

Donated medication cannot be accepted from a patient or a member of the public for re-dispensing under any circumstances. [20 CSR 2220-2.685(6)(A)]

Patients or the patient's designee must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site or unavailable to provide remote patient counseling, a written offer to counsel with a contact telephone number for a pharmacist must be provided with the medication. [20 CSR 2220-2.685(4)(B)]

Effective November 30, 2022, a Class Q pharmacy receiving a completed and labeled prescription from another pharmacy for an indigent patient is not considered to be shared services. [20 CSR 2220-2.685(9)] The receiving and providing pharmacy do not need a Class J permit for this activity.

Licensees should review 20 CSR 2220-2.685 in its entirety prior to applying for a Class Q pharmacy permit to ensure eligibility. Applicants are not eligible for a Class Q pharmacy permit if they will be dispensing or providing pharmacy services for anyone other than indigent patients as defined by the rule.

D.16 Class R Remote Dispensing Pharmacies

Section 338.215 defines a Class R Dispensing Site pharmacy as:

> *Any location in this state where the practice of pharmacy occurs and that is licensed as a pharmacy to dispense prescription drugs and is staffed by one or more qualified pharmacy technicians, as defined by the board, or intern pharmacists, whose activities are supervised by a pharmacist at a supervising pharmacy through a continuous real-time audio and video link.*

A remote dispensing site does not include a dispensing prescriber's office, an automated device, or a remote data entry site under 20 CSR 2220-2.725. Qualified pharmacy technicians and intern pharmacists may compound, prepare and dispense medication at a Class R remote dispensing site under remote supervision by a Missouri-licensed pharmacist located at the supervising pharmacy (see additional requirements below).

To be eligible for licensure, a Class R pharmacy must be located in Missouri and:

1. Must be under the supervision of a Missouri-licensed supervising pharmacy that shares common ownership with the Class R site and meets the requirements of § 338.215 and 20 CSR 2220-2.680 (see supervising pharmacy section below); and
2. Must be located at least ten (10) miles away from another Board licensed pharmacy that is open to, or offers pharmacy services to, the general public.* The 10-mile restriction does not apply to remote dispensing sites that are part of a community mental health center, federally qualified health center, rural health clinic, or outpatient clinic, as defined by 20 CSR 2220-2.680. Applicants are responsible for demonstrating compliance with the 10-mile restriction; A downloadable listing of Missouri pharmacies is available on the Board's website that can be sorted by address, county and zip code.*

**See § 338.215 and 20 CSR 2220-2.680 for submitting location/mileage waiver requests to the Board.*

Once licensed by the Board, Class R pharmacies may provide Class A (Community/Ambulatory), Class B (Hospital Pharmacy), or Class C (Long-Term Care) pharmacy services under their Class R permit. [20 CSR 2220-2.680(2)(C)]. Class R pharmacies must apply for and hold the applicable pharmacy permit classification for any additional pharmacy services provided at the Class R site (e.g., Class D (Non-Sterile Compounding), Class H (Sterile Compounding, etc.).

The Class R and supervising pharmacy may engage in shared services without a Class J permit. All other involved pharmacies must have a Class J shared services permit and comply with 20 CSR 2220-2.680, including the supervising pharmacy. [20 CSR 2220-2.680(2)(C)]

Class R operations must immediately cease if: (1) the supervising pharmacy and Class R pharmacy are no longer under common ownership, (2) the supervising pharmacy is no longer eligible to supervise the Class R pharmacy, or (3) the supervising pharmacy's Missouri pharmacy permit is not current and active. [20 CSR 2220-2.680(3)(D)] Class R operations may resume once the supervising pharmacy's permit returns to active

or eligible status or common ownership is re-established.

Supervising Pharmacies

Class R pharmacies must be under the supervision of a Missouri-licensed supervising pharmacy that is responsible for supervising the Class R site and Class R operations, in conjunction with the Class R permit holder. The supervising pharmacy must be located in Missouri and no more than 50 miles away from the Class R site, unless otherwise approved by the Board. [§ 338.215.10] Section § 338.215.4 provides the supervising pharmacy and Class R pharmacy must also share common ownership. Licensees should consult with legal counsel on the ownership requirements; The Board cannot provide legal advice.

Effective policies and procedures must be in place to ensure appropriate oversight of Class R operations at all times. At a minimum, the supervising pharmacy and Class R pharmacy must both maintain a current and accurate written policy and procedure manual that includes:

- A description of how the supervising pharmacy and Class R pharmacy will comply with federal and state laws/ rules;
- Procedures for supervising the remote dispensing site pharmacy and providing required patient counseling;
- Procedures for reviewing the Class R pharmacy's prescription drug inventory and drug records;
- Security policies/procedures for protecting the confidentiality and integrity of patient information;
- A written recovery plan from an event that interrupts or prevents a pharmacist from supervising the Class R pharmacy;
- The specific duties, tasks, and functions qualified pharmacy technicians/intern pharmacists are authorized to perform at a Class R pharmacy under remote supervision;
- Procedures for maintaining an up-to-date inventory of all controlled substances (see controlled substances section below for perpetual inventory requirements), and;
- Policies/procedures for ensuring appropriate pharmacist review of verbal prescription orders received by a Class R pharmacy without a pharmacist present. [§ 338.215; 20 CSR 2220-2.680(5)(C)]

The supervising pharmacy and Class R pharmacy must share a common database or have access to each other's prescription record-keeping system. The common database or shared system must allow both the supervising pharmacy and the Class-R pharmacy to have real-time, online access to the patient's complete profile. [20 CSR 2220-2.680(3)(B)]

A prominent sign must be posted at the Class R pharmacy notifying patients that the Class R pharmacy is supervised by the supervising pharmacy along with the supervising pharmacy's name, address and telephone number. [20 CSR 2220- 2.680(4)(C)]

Class R pharmacy applications are available on the Board's website. Applications must be accompanied by the applicable fee and designate a pharmacist-in-charge (PIC) for the Class R site who holds a current and active Missouri pharmacist license. The same PIC may be designated for both the supervising pharmacy and Class R site. However, PICs serving in a dual capacity should exercise caution and are reminded that you will be held personally responsible for compliance at both pharmacies.

Staff Training

Only qualified pharmacy technicians and intern pharmacists who have completed additional training may

assist at a Class R pharmacy without a pharmacist physically present. A qualified pharmacy technician is defined as a currently registered Missouri pharmacy technician who:

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies, and
2. Has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency. The contents and form of training/competency assessment are in the licensee's discretion; and
3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year. The 1-year of pharmacy technician experience may have been obtained at the supervising pharmacy, another Missouri licensed pharmacy or at a Missouri hospital. [20 CSR 2220-2.680(1)(E)]

Qualified pharmacy technicians being remotely supervised at a Class R site must meet all three of the above requirements.

Intern pharmacists being remotely supervised at a Class R pharmacy must have completed employer approved training in the activities performed at the Class R site and have an initial and annual documented assessment of competency. Once again, the content and form of training/competency assessment are in the licensee's discretion.

Documentation of the required training/competency assessment for qualified pharmacy technicians and intern pharmacists must be maintained in the pharmacy's records for a minimum of two (2) years.

Standards of Operation/Remote Supervision

Class R pharmacies must comply with all laws and regulations applicable to the pharmacy services provided. Class R pharmacies must be staffed by a current and active Missouri licensed pharmacist at least eight (8) hours a month. [§ 338.215.8] Additionally, the Class R's PIC must visit the Class R site weekly during the first month of operation to verify compliance and monthly thereafter. The date of the monthly PIC compliance visit must be documented in the pharmacy's records. [20 CSR 2220-2.680(4)(A)]

Intern pharmacists and qualified pharmacy technicians assisting at a Class R site must be supervised by a Missouri-licensed pharmacist who is physically present at the Class R site, or remotely supervised by a Missouri-licensed pharmacist who is located at and employed by the supervising pharmacy using technology that provides a continuous real-time audio and video link [§ 338.215.3].

- Pharmacists remotely supervising a Class R site must be competent to perform the services being supervised. To ensure patient safety, a pharmacist may not remotely supervise more than two (2) Class R pharmacies at the same time. [§ 338.215.4; 20 CSR 2220-2.680(4)(D)]
- Licensees/permit holders should use their discretion to determine the technology needed to provide adequate remote supervision. The required technology must provide both audio and video capability, and must allow the supervising pharmacist to provide the personal assistance, direction and approval needed to verify and ensure remote tasks are safely and properly performed. [20 CSR 2220-2.680(4)(D)]
- Class R pharmacy operations must immediately cease if the required supervision technology is unavailable or not in working order, unless a pharmacist is present at the Class R pharmacy and able to supervise. The no pharmacist on duty sign required by 20 CSR 2220-2.010 must also be posted. Remote supervision may not resume until the required supervision technology is available and functioning. [20 CSR 2220-2.680(4)(E)]

- Section 338.215.3 provides the supervising pharmacist must be "employed by" the supervising pharmacy; Licensees should consult with legal counsel to ensure compliance with employment requirements.

Medication Dispensing:

Qualified pharmacy technicians and intern pharmacists may compound, prepare and dispense medication at a Class R pharmacy without a pharmacist physically present, if the qualified pharmacy technician/intern pharmacist is remotely supervised by a Missouri-licensed pharmacist, in compliance with § 338.215 and 20 CSR 2220-2.680.

The final contents and affixed label of each prescription/medication order must be physically verified by a pharmacist in-person or remotely verified by a Missouri-licensed pharmacist at the supervising pharmacy using technology that includes bar coding and visual review of the medication contents and affixed label via remote video. [§ 338.215.5] Section 338.215.5 provides pharmacists remotely verifying prescriptions/medication orders must be located at the Class R's supervising pharmacy. Pharmacists cannot perform remote product verification outside of the supervising pharmacy.

If a Class R pharmacy is being remotely supervised, the "name and specific activities" of each pharmacist, intern pharmacist or pharmacy technician involved in the dispensing process must be documented in the Class R pharmacy's prescription records. [§ 338.215.5] Activities requiring documentation should be listed in the Class R/supervising pharmacy's policies and procedures. At a minimum, the Board will request documentation of the licensee/registrant responsible for entering prescription/medication order data, filing, preparing or compounding medication, and dispensing the final prescription/medication order to the patient/patient's designee. In lieu of documenting the licensee's/ registrant's name, the Board will not take enforcement action if the licensee's/registrants initials or another unique identifier is documented in the pharmacy's prescription records, provided the applicable licensee/registrant can be readily identified if requested by the Board or a Board inspector.

Note: The final prescription/medication order dispensed by a Class R pharmacy must be verified by a pharmacist under 20 CSR 2220-2.680(5)(A). Technicians/Intern Pharmacists at a Class R site cannot perform technology assisted verification at a Class R site.

Patient Counseling

Patient counseling must be provided by a Missouri-licensed pharmacist at the supervising pharmacy for all new and refill prescriptions dispensed by a Class R pharmacy when a pharmacist is not physically present, unless refused by the patient. [§ 338.215.6; 20 CSR 2220-2.680(5)(B)].

1. Patient counseling is mandatory for all prescriptions dispensed by a Class R pharmacy without a pharmacist present unless refused by the patient; An offer to counsel is not sufficient. Remote patient counseling may not be delegated to an intern pharmacist.
2. Pharmacists providing remote patient counseling must use a HIPAA-compliant real-time video and audio link to counsel. Additionally, the counseling pharmacist must be located at and employed by the supervising pharmacy. Patient counseling may not be provided by a pharmacist from home or from another location/pharmacy other than the supervising pharmacy. Licensees should consult with legal counsel to ensure compliance with the employment requirement. [§ 338.215.6]
3. Pharmacists providing remote patient counseling must have access to all relevant patient information maintained by the Class R pharmacy. Additionally, the identity of the counseling

pharmacist must be documented in the pharmacy's prescription records.

4. Section 338.215.6 provides "the system being used to perform [remote patient] consultation must retain the initials or unique identifier of the pharmacist who performs the consultation." The statutory intent of this requirement is unclear. However, the Board will not take enforcement action if the name or identity of the pharmacist performing remote patient counseling is documented in the pharmacy's prescription records and readily available on request.

Prescription Limits

Class R pharmacies must apply for a Class A, B or C pharmacy permit if the average number of prescriptions dispensed by the Class R site during the previous calendar quarter exceeds one-hundred and fifty (150) prescriptions/medication orders per day, excluding immunizations given by protocol. [§ 338.215.9] 20 CSR 2220-2.680 establishes the following calendar quarters:

- Quarter 1: January 1 – March 31
- Quarter 2: April 1 – June 30
- Quarter 3: July 1- September 30, and
- Quarter 4: October 1 – December 31.

Class R pharmacies must calculate the number of prescriptions/medication orders dispensed during the previous calendar quarter on or before the 10th day following the close of each quarter (January 10th, April 10th, July 10th and October 10th). [§ 338.215.9; 20 CSR 2220-2.680(2)(D)]

If the average number of prescriptions/medication orders dispensed by the Class R pharmacy during the previous calendar quarter exceeds the one-hundred and fifty (150) limit, the Class R pharmacy must apply to the Board for a Class A, B or C pharmacy permit within ten (10) days of discovery. [§ 338.215.9; 20 CSR 2220-2.680(2)(D)] A pharmacy Classification Change application must be submitted to add the required classification along with the applicable fee.

Class R pharmacy services must terminate once a Class A, B or C permit is issued by the Board. However, Class R operations may resume if the daily average number of prescriptions dispensed by the pharmacy does not exceed 150 prescriptions/medications orders during a subsequent calendar quarter (see calendar quarters listed above). The pharmacy's Class A, B, or C pharmacy classification must be surrendered to the Board within five (5) days of resuming Class R operations. [20 CSR 2220-2.680(2)(D)] A second Classification Change application would be required to return to just a Class R permit.

*** *The Class R 150 prescription/medication order limit does not include filled prescriptions/medication ordersthat are not dispensed to or picked up by the patient.*

Controlled Substances: Controlled substances must be handled, stored and dispensed in compliance with applicable state and federal controlled substance laws. A perpetual inventory must be maintained for all controlled substances at a Class R pharmacy that is reconciled twice per month. [§ 338.215.8; 20 CSR 2220-2.680(4)(B)] The PIC for the Class R pharmacy must review the reconciliation for accuracy/discrepancies during the PIC compliance visits required by 20 CSR 2220-2.680(4)(A).

Security: Adequate security and supervision must be maintained at a Class R pharmacy at all times to prevent medication theft/diversion and unauthorized access to the pharmacy or confidential records/data. [20 CSR 2220-2.680(6)] To ensure proper security, Class R pharmacies must have an alarm mechanism that alerts the supervising pharmacy or the Class R's PIC in the event of unauthorized access to the Class R site. Unauthorized access to a Class R pharmacy must be documented and reported to the board in writing

within seven (7) days of discovery. [20 CSR 2220-2.680(6)]

Record-Keeping: Class R pharmacies must comply with all record-keeping and documentation requirements of Chapter 338, RSMo, and the Board's rules. Additionally, Class R pharmacies must maintain documentation of:

1. The number of prescriptions dispensed by the Class R pharmacy each calendar quarter; and
2. Proof qualified pharmacy technicians assisting at a Class R pharmacy have completed the experience, training, and competency assessment required by 20 CSR 2220-2.680.

Records required by 20 CSR 2220-2.680 must be manually or electronically maintained for two (2) years at the Class R pharmacy and must be readily retrievable on request of the Board or the Board's authorized designee. If the Class R pharmacy is no longer operating, required records must be maintained at the supervising pharmacy. Prescription records must be maintained for five (5) years as required by Chapter 338 and the Board's rules. [20 CSR 2220-2.680(7)]

D.17 Quality Assurance

According to a John Hopkins study, more than 250,000 U.S. deaths occur annually due to medication errors. Researchers noted "most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, [and] the absence or underuse of safety nets, and other protocols[.] "

An effective quality assurance/improvement (QA/QI) program is a critical part of preventing medication errors and will help foster a culture of safety that allows other pharmacists/healthcare providers to prevent and learn from errors and mistakes.

Quality assurance includes more than just quality controls. Quality controls are intended to ensure a specific function/activity meets designated quality requirements. While quality controls can be an important part of a QA/QI plan, the pharmacy's QA/QI program should focus on building and ensuring system safety, quality, and accuracy as a whole.

The Board recommends that all permit holders/pharmacies adopt a QA/QI program that includes:

- A systematic, ongoing process for investigating, reporting, and analyzing medication errors, adverse events, and significant "near-misses" that are caught before reaching/impacting the patient,
- Staff training and education, and
- Accessible staff/patient reporting mechanisms, including mechanisms for confidentially reporting quality concerns without retaliation.

The Board also recommends that permit holders review QA/QI data to identify ways to develop or improve pharmacy systems and workflows processes.

The above suggestions are best-practice recommendations from the Board. However, quality improvement/quality assurance procedures are required for the following:

- Automated Dispensing & Storage Systems 20 CSR 2220-2.900(2)(A)
- Automated Filling Systems 20 CSR 2220-2.950(5)(M)
- Compounding (sterile & non-sterile) 20 CSR 2220-2.400(8)(B)
- Class F: Renal Dialysis Pharmacies 20 CSR 2220-2.600(2)(E)
- Class J: Shared Services Pharmacy 20 CSR 2220-2.650(1)(D)

- Intern/Technician technology assisted verification 20 CSR 2220-2.012
- Pharmacist electronic final product verification 20 CSR 2220-2.011(3)
- Remote data entry sites 20 CSR 2220-2.725(4)
- Pharmacist conducted technology assisted final prescription/medication order verification 20 CSR 2220-2.012(5)

E.1 GENERAL REQUIREMENTS

Pharmacies must be safely operated at all times in compliance with applicable state and federal law. Section E summarizes general operational standards applicable to all pharmacies, however, specific pharmacy allowances/requirements will differ based on the pharmacy's permit classification and activities. Licensees should thoroughly review Chapter 338 and the rules of the Board to ensure compliance.

E.2 FACILITIES

Pharmacies must be maintained in a clean and sanitary condition at all times, including, all areas where pharmacy services are provided or medication is stored (e.g., pharmacy counters, shelves, pharmacy equipment, and vaccine administration areas). The Board strongly recommends that pharmacies designate specific time periods and give staff designated time to clean and disinfect the pharmacy and patient care areas on a regular basis.

- Appropriate lighting, ventilation, and humidity must be maintained in all areas where drugs are stored and dispensed. Medication may not be stored on the floor *(see E.5 below)*
- Trash must be disposed of in a timely manner.
- Appropriate sewage disposal and a hot and cold water supply must be available within the pharmacy. The required water supply may not be located in a bathroom.
- Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.
- Drop down ceilings or other openings that will allow unauthorized access to the pharmacy are prohibited. For pharmacies located in facilities that have public access after the pharmacy's normal hours of operation, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. [20 CSR 2220-2.010(1)(K)]
- Effective August 30, 2022, staff must wear disposable gloves when physically touching individual dosage units. [20 CSR 2220-2.010(1)(I)]
- The pharmacy must be free from insects and vermin. Animals of any kind are not allowed in the pharmacy, except for service animals as defined by the American with Disabilities Act. The Board recommends that pharmacies establish policies/procedures for regularly monitoring and treating for infestations. [20 CSR 2220- 2.010(G)]

Effective August 30, 2022, all pharmacies located in Missouri must post a regulatory sign that indicates the pharmacy is licensed and regulated by the Missouri Board of Pharmacy and includes the Board's current mailing and e-mail addresses. [20 CSR 2220-2.010(1)(L)3.] The required sign must be prominently posted in close proximity to the pharmacy in a manner and location that is easily viewable and readable by the public. Posting is required for all pharmacies located in Missouri, even if the pharmacy is not open to the public (e.g., "closed door" pharmacies).

Electronic signs must be constantly visible to the public during the pharmacy's normal business hours without interruption. [20 CSR 2220-2.010(1)(L)3.] Scrolling electronic sign displays with different messages are not compliant.

The Board will provide a free copy of the Board regulation sign to all Missouri located pharmacies (*fees may apply for replacement signs*). An electronic version of the Board regulatory sign is also available on the

Board's website for copying/reproduction. Pharmacies may create their own signs or display an electronic sign, provided the sign includes the same wording and the sign's lettering equals or exceeds the sign issued by the Board.

E.3 POSTING LICENSES

Pharmacy permits must be current and conspicuously posted in the pharmacy permit area [§ 338.300, RSMo].

Effective August 30, 2022, pharmacist, intern pharmacist and pharmacy technician licenses/registrations do not have to be posted in the pharmacy. Instead, individual licenses/registrations may be maintained in a central location on the pharmacy's premises with a 2" x 2" photo attached to the actual license (e.g., on the pharmacy wall or in a binder or cabinet). [20 CSR 2220-2.010(1)(L)] *Note: The photo requirement is new for technicians and intern pharmacists.* Individual licenses/registrations must be immediately retrievable during an inspection or available to the public if requested.

Licensees/registrants working at more than one (1) pharmacy should maintain their license/registration at the pharmacy that the individual considers to be their main or primary work location (e.g., where the licensee/registrants works the most time per week/month), and must have proof of licensure in their possession when assisting in the practice of pharmacy at any other pharmacy location (wallet card, current online verification from the Board's website).

E.4 REQUIRED EQUIPMENT/REFERENCES

Adequate resources must be provided to allow licensees/registrants to safely and accurately provide pharmacy services. [20 CSR 2220-2.010(1)(C) – (D)] . Additionally, pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services provided, as recognized by the latest edition of the *United States Pharmacopeia (USP), the United States Pharmacopeia/Drug Information (USP/DI) or Remington's: The Science and Practice of Pharmacy*. [20 CSR 2220-2.010(1)(C) – (D)] The Board does not approve specific brands or products, however, pharmacy equipment will be inspected for proper functioning on inspection. Inspectors may also request maintenance/calibration records when needed (see section E5 for temperature monitoring requirements for medication storage areas).

At a minimum, the following references/resources must be physically maintained in or immediately accessible in electronic form at the pharmacy:

1. A current print or electronic edition of statutes and rules governing the pharmacy's practice, including, but not limited to, Chapter 338 and 195, RSMo, Board of Pharmacy rules (20 CSR 2220-2.220) and, if applicable, BNDD rule chapter 19 CSR 30 governing controlled substances.
2. Generally recognized reference(s) or other peer-reviewed items that include the following items/topics:
    - All drugs approved by the United States Federal Drug Administration (FDA), as appropriate to the practice site. *Note: This resource may be different based on the pharmacy services provided (e.g., nuclear pharmacy vs. community/ambulatory pharmacy)*
    - Pharmacology of drugs
    - Dosages and clinical effects of drugs; and
    - Patient information and counseling

The above information may be maintained in a single reference or multiple references, provided the

information is regularly retrievable on inspection.

E.5 DRUG STORAGE & TEMPERATURE MONITORING

Drugs and drug-related devices must be properly stored and maintained at all times. Drugs must be stored in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA's approved drug product labeling or the United States Pharmacopeia (USP). [20 CSR 2220-2.010(2)].
See below for temperature monitoring requirements.

1. Appropriate lighting, ventilation, and humidity must be maintained in all areas where drugs are stored and dispensed. Medication may not be stored directly on the floor (e.g., stock bottles or prescription containers sitting directly on the floor). Medication stored in totes or outer storage containers/bags would be compliant, provided the medication is not directly on the floor and proper sanitation/conditions are otherwise maintained.
2. Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from medication and medication-related devices. Open food or beverages used in compounding or intended for patient use with medication may be stored in the same area as drugs and drug-related devices, as long as the items are separated from other inventory and sanitary conditions are maintained at all times. [20 CSR 2220-2.010(2)(C)].
3. Outdated, distressed, misbranded or adulterated drugs and devices must be quarantined in an area that is clearly identified and physically separated from medication maintained for dispensing, distribution or other pharmacy use. [20 CSR 2220-2.010(2)(B)]. Effective August 30, 2022, medication for personal employee use must also be quarantined and physically separated from medication maintained for pharmacy use. [20 CSR 2220-2.010(2)(B)]. Quarantine areas must be clearly identified to ensure employee medication and outdated, misbranded, or adulterated drugs do not enter/re-enter the pharmacy's active inventory.
4. Effective August 30, 2022, staff must wear disposably gloves when physically touching individual dosage units. [20 CSR 2220-2.010(1)(I)]

TEMPERATURE MONITORING:

Temperatures in drug storage areas must be recorded and reviewed at least once every day the pharmacy is in operation. [20 CSR 2220-2.010(2)(A)]. This includes all rooms, areas, refrigerators, or freezers where drugs are stored. Temperature reviews may be delegated to pharmacy staff, however, staff should be trained on what appropriate temperature(s) are and what to do if a temperature reading is out of range.

In lieu of daily temperature recordings/reviews, pharmacies may use a continuous temperature monitoring system if the system: (1) maintains ongoing documentation of temperature recordings, and (2) alerts a pharmacist when temperatures are outside of the required range and provides the amount of variance. [20 CSR 2220-2.010(2)(A)]. Real-time alerts are recommended (e.g., audible alert, electronic notification, phone call). At a minimum, continuous monitoring systems should alert the pharmacist in sufficient time to allow the pharmacist or his/her designee to quickly respond to protect drug integrity. A continuous temperature monitoring system is optional and is not required if the pharmacy otherwise records and reviews medication storage area temperatures daily.

Temperature documentation records must be maintained in the pharmacy's records for two (2) years (manual, electronic or ongoing recordings). The Board also recommends documenting temperature alerts/excursions and any corrective action taken by the pharmacy.

Licensees should review package labeling as some products have special storage and temperature requirements and may not be stored in certain refrigeration/freezer units (e.g., dormitory style refrigerators). Other products may have limited expiration dating once the package is opened.

E.6 PHARMACY SUPERVISION

Pharmacy staff and pharmacy operations must be properly supervised at all times to ensure safe patient care activities and compliance with state/federal law. Required supervision for pharmacy technicians/intern pharmacists will vary based on staff activities and location; Technology-assisted supervision is authorized in some instances.

See section C.2 and C.3 for detailed information on staff supervision requirements for all practice settings. The following sections/Board rules address pharmacy supervision for the practice settings/activities identified below:

- 20 CSR 2220-2.710: Technology Assisted Supervision (See C.2, C.3)
- 20 CSR 2220-2.725: Remote data entry sites (See H.3)
- 20 CSR 2220-2.600: Class F Renal Dialysis Pharmacies (See D.2)
- 20 CSR 2220-2.675: Class L Veterinary pharmacies (See D.13)
- 20 CSR 2220-2.685: Class Q Charitable Pharmacies (See D.15).
- 20 CSR 2220-2.680: Class R Remote Dispensing Sites (See D.16).
- 20 CSR 2220-6.055: Non-dispensing activities outside of a pharmacy (See C. 5)

Licensees should review the above rules and Practice Guide sections for compliance requirements applicable to each setting/activity.

**See section O & section P for additional information on authorized pharmacy technician and intern pharmacist duties.*

E.7 STAFFING

Pharmacies must maintain sufficient staffing to ensure patient care services are safely provided at all times in compliance with applicable standards of patient care. Adequate staffing and resources must be provided to allow licensees/registrants to safely and accurately provide pharmacy services. [20 CSR 2220-2.010(1)(C)].

All pharmacy staff must be appropriately licensed or registered to work. Licenses/registrations must be either posted in the pharmacy or maintained in the pharmacy in a central location with a 2x2 photo attached. [20 CSR 2220-2.010(1)(L)]. *Note: The photo requirement is new for intern pharmacists and technicians.* License status may change throughout the year due to discipline, non-renewal, or tax compliance issues. The Board recommends designating a specific person who is responsible for checking licensure status at regularly set intervals. (See O.12 for additional technician disciplinary information).

Missouri does not mandate staffing ratios (e.g., pharmacist-to-technician). However, pharmacies must maintain adequate staffing to safely and accurately provide pharmacy services. [20 CSR 2220-2.010(1)(C)]. Permit holders must have policies and procedures in place for regularly reviewing staffing and resource needs with the pharmacist-in-charge, including policies and procedures for requesting additional staff or staffing modifications. [20 CSR 2220-2.090(1)(D)]

PICs/permit holders should consider relevant factors that might impact patient care when determining appropriate staffing levels, including, staff training/experience, prescription volume/vaccinations, and other

clinical cognitive patient services being provided. Additional staffing may be needed at certain periods of the day or during peak periods such as immunization season.

The Board recognizes that unplanned absences can, and will, occur. However, permit holders should establish a contingency plan to address unplanned absences before they happen. Pharmacies should also have procedures for staff to report staffing shortages or to request additional help when needed, especially after-hours and on weekends. Make sure you communicate the plan to pharmacy staff and train pharmacy management on how to respond.

In the event of a staff shortage, the Board also recommends that permit holders and the pharmacist-in-charge consider if the pharmacy can continue to offer the full range of pharmacy services or maintain normal pharmacy hours. Temporarily suspending drive-thru service, changing pharmacy hours, or modifying vaccine services may provide needed relief until the pharmacy is properly staffed. If the pharmacy chooses to close early or temporarily change hours, the Board recommends notifying patients as early as possible (e.g., posting a sign, changing pharmacy voicemail, via the pharmacy's website).

Board Inspectors have observed pharmacies that were almost a week behind in dispensing due to a staffing emergency, but continued to accept new prescriptions without telling patients that their prescriptions may not be filled for days. Delayed dispensing can threaten patient care. Let patients know if the pharmacy is experiencing lengthy delays and give them a reasonable timeline for when to expect their medication.

Failure to maintain safe staffing levels may constitute grounds for Board action under Missouri law.

The Board has strong concerns with pharmacies not answering phones or placing patients on hold for an excessive amount of time. Pharmacist consultation is a vital part of patient care. Additionally, other pharmacies and prescribers may need to contact the pharmacy to discuss medication, request prescription transfers, or coordinate care. Permit holders should review the pharmacy's operations on a regular and ongoing basis to make sure patients can speak to a pharmacist within a reasonable amount of time.

REQUIRED STATE/FEDERAL WAIVERS

Both state and federal law prohibit an employer from hiring individuals with certain controlled substance related convictions without an employment waiver [see 21 CFR 1301.76(a); 19 CSR 30-1.034]. Specifically, employers are required to obtain a DEA waiver for employees with felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration. A waiver is required for every location where the individual is employed

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA. (See also the DEA Pharmacist's Manual)

E.8 IDENTIFICATION BADGES

Effective August 30, 2022, all Board licensees and registrants must wear an identification badge or a similar identifying article that identifies the licensee's/registrant's name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist). [20 CSR 2220-2.010(1)(L)1.] Pharmacies should establish policies/procedures that establish the types of allowed ID badges/articles and approved name format (full name, first name and last initial, first name only). Reusable and hand-written badges are acceptable as well as embroidered clothing/articles, if authorized by the pharmacy (e.g.,

smocks/jackets).

- Licensees have asked about using commonly known names, instead of the official name listed on the Board's license/registration. For example, licensees have asked if Anthony Michael Doe's ID badge can just read "Michael" if that is the name the licensee commonly uses. This is in the permit holder's discretion, however, the public and the Board should be able to easily identify staff if needed.
- The ID badge must include the licensee's/registrant's name and title (pharmacist, technician, intern pharmacist). Abbreviations may be used if the public can easily identify the individual's license/registration title (e.g., RPh, PharmD, Intern or Tech.). Designations that the public may not be able to readily identify should not be used (e.g., CPhT). Patients should be able to easily distinguish when they are talking with a pharmacist and when they are talking with an intern pharmacist or pharmacy technician.

  - To ensure environmental quality, staff do not have to wear an ID badge/article while engaged in sterile compounding or in a controlled area as defined by 20 CSR 2220-2.200 (Sterile Compounding).

E.9 WORKING CONDITIONS

Section 338.240, RSMo, provides pharmacies must be operated "in a manner not to endanger the public health or safety." Additionally, pharmacies are prohibited from introducing or enforcing any policies, procedures, systems, or practices that jeopardize, inhibit, or threaten patient safety or the safe provision of pharmacy services. [20 CSR 2220-2.010(1)(A).] This includes pharmacy metrics and requirements that do not provide enough time for staff to safely provide patient care, or that do not give pharmacists sufficient time to safely and properly perform needed clinical cognitive patient services (e.g., # of prescriptions or vaccines per hour).

Permit holders should thoroughly review pharmacy operations to ensure safe and proper working conditions at all times. This includes pharmacy staffing. Talk with pharmacy staff to gather input. Pharmacy staff know what the pharmacy's day-to-day operations are really like and have to be a part of the solution. If issues are identified, work with pharmacy staff to develop a collaborative solution. Patient care is a team-based effort and everyone can be part of the solution. While the Board recognizes business needs, patient safety should not be jeopardized for company profits.

To ensure patient safety, the pharmacist-in-charge (PIC) must be consulted and given an opportunity to provide input prior to implementation of any pharmacy policy, procedure, system, or practice that will modify or expand the delivery of pharmacy services, except in the event of an emergency or other urgent need. [20 CSR 2220-2.090(1)(A)] PICs must also have authority to temporarily suspend or restrict pharmacy operations or the activity of licensees/registrants, if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction or approval from the permit holder. [20 CSR 2220-2.090(1)(C)] A proactive communication plan between the PIC and permit holder is key and will prevent interruptions in patient care!

The Board has received multiple complaints/concerns from licensees who were reportedly unable to take restroom or other basic breaks during their shifts. When breaks are given, licensees/registrants reported still being expected/required to work during their purported "break time." Licensees have also raised concerns with being required to work an extended number of consecutive days without time off.

According to a study funded by the U.S. Agency for Healthcare Research and Quality (AHRQ), fatigue is "a latent hazard and 'an unsafe condition' in health care that leads to increased medical error rates." Review the pharmacy's work and break schedules for issues that can threaten patient care. Licensees/registrants need time to mentally and physically recoup to continue providing safe pharmacy services.

Pharmacies should also review their workflow processes to identify system design issues that may be negatively impacting working conditions. A well-designed system will help alleviate workload stress and enhance patient safety. Talk to pharmacy staff and look for opportunities to enhance system design/workflow, such as:

- Eliminating redundant/duplicate activities
- Leveraging technology (e.g., having vaccine patients schedule appointments or complete necessary paperwork online)
- Simplifying the work flow process
- Minimizing interruptions for pharmacy staff (interruptions can be a significant contributing factor for medication errors)
- Enhancing information flow, and
- Delegating non-discretionary tasks to properly trained pharmacy technicians or intern pharmacists.

Pharmacy staff cannot perform at optimal levels if the system is not designed for success. Asking staff to manage an unsafe workload is unreasonable and dangerous. Patients deserve the best in patient care. Pharmacy staff must have sufficient time, resources and support to properly perform their professional duties.

Failure to maintain a safe working environment constitutes grounds for disciplinary action in Missouri, as authorized by § 338.055, § 338.210, § 338.250 and § 338.285. Act now to find a solution that protects patients and works for your pharmacy practice setting. The Board will be investigating Missouri pharmacies if pharmacy working conditions are identified or exist that could threaten or endanger patient safety.

E.10 SECURITY

Pharmacies must maintain adequate security and locking mechanisms to prevent unauthorized access to the pharmacy and ensure the safety and integrity of drugs and confidential records. [20 CSR 2220-2.010(1)(H)]. To prevent unauthorized access, drop down ceilings or other openings that will allow unauthorized access to the pharmacy are prohibited. [20 CSR 2220-2.010(1)(K)] If the pharmacy is located in a facility that the public can access after the pharmacy's normal hours of operation, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. [20 CSR 2220-2.010(1)(K)]

Licensees should consider counter heights, gates/doors, wall/ceiling barriers and areas that might be easily accessed by the public. The Board has investigated cases where medication was stolen by customers who were able to reach into will-call bins or over prescription counters. At other times, prescriptions were left unattended at the register. *Note: Licensees must also comply with all controlled substance security requirements.*

The following security breaches must be reported to the Board:

WHAT NEEDS TO BE REPORTED?	WHEN?	STATUTE/RULE
Security Breach (Bd. registered offsite warehouse/storage facility)	Within fifteen (15) days of breach	20 CSR 2220-2.010(1)(J)
Security Breach (Data processing systems or confidential documents at an offsite location where non-dispensing activities are performed)	Within seven (7) days of breach	20 CSR 2220-6.055(2)
Security Breach (Remote Data Entry Site)	Within seven (7) days of breach	20 CSR 2220-2.725(3)(A)

Additional diversion prevention tips and resources are available on the Board's website.

Resources/videos on preventing or handling pharmacy robberies are available at www.rxpatrol.com. This website is provided for informational purposes only and is not sponsored or endorsed by the Board.

The Board has reviewed several cases where technicians were able to illegally change prescription records or inventory figures using a pharmacist's computer credentials. In most instances, the pharmacist either stepped away from the computer without logging off or left their log-on credentials unattended. This is a significant security/diversion risk. Computer passwords or log- on information should be protected from unauthorized use at all times. The Board recommends that pharmacists log off or lock their computers when away from their workstations.

E.11 VACUUM TUBE DELIVERY SYSTEMS [20 CSR 2220-2.800]

Vacuum tube systems may be used to deliver medication to a patient if the system is designed and engineered to ensure drug security and to ensure that drugs are correctly and efficiently delivered. The system must be dedicated solely to delivering medication from within a licensed pharmacy and cannot be used for other departments or combined/attached to any other system (e.g., grocery delivery). The system must be turned off and medication may not be delivered if the pharmacy is closed or when there is no pharmacist on duty.

Vacuum tube systems must allow pharmacy personnel and the consumer to communicate effectively both orally and in writing. A direct and identifiable line of sight must be maintained with the consumer. Alternatively, a video camera and audio system may be used to identify consumers. The video monitor/audio system must be in good working order or use must be discontinued until corrections/repairs are made. At a minimum, video monitors must be at least twelve inches (12") wide. Backlighting or other factors that may inhibit video/audio performance must be considered before operation.

Recipients must be positively identified before drugs are delivered via a vacuum tube system. [*See 20 CSR 2220-2.800(2) for vacuum systems installed before September 1, 1998].*

E.12 AUTHORIZED MEDICATION SOURCES

Licensees may only receive/purchase medication from:

1. A Missouri-licensed drug distributor, drug outsourcer or third-party logistics provider,
2. A Missouri licensed pharmacy, or
3. A pharmacy licensed in another U.S. state or territory. (See D.10 for Class-B pharmacy/hospital

exemptions)

Licensees receiving medication from a non-resident pharmacy that is not licensed in Missouri must comply with the following:

1. The receiving Missouri pharmacy must maintain proof the non-resident pharmacy has a current pharmacy license in the state/territory where the drug is shipped/distributed from,
2. An invoice record must be maintained which documents the name and address of the non-resident pharmacy, the purchase/transfer date, and the name, strength, and quantity of the drug received, and
3. The total amount of medication distributed/received from a non-resident pharmacy that is not licensed in Missouri cannot exceed five-percent (5%) of the pharmacy's annual prescription drug sales. [§ 338.315.2]

See 20 CSR 2220-5.020(1) for additional drug distribution exemptions.

Medication receipts/transfers must be documented by invoice (non-controlled and schedule III-V drugs), or via CSOS or a DEA 222 form (schedule II).

****See 20 CSR 2220-5.020 for drug distributor licensure exemptions; Licensees may receive medication from an exempt entity as authorized in the rule.*

E.13 DRUG SAMPLES

Drug samples may not be dispensed by, or maintained in, the pharmacy, except as otherwise authorized by state and federal law, including, but not limited to 21 U.S.C. Section 353 and the federal Prescription Drug Marketing Act of 1987. [20 CSR 2220-2.010(2)(E)].

E.14 OFFSITE STORAGE SITES

Medication and confidential pharmacy records may be stored off-site at a different location/address than the pharmacy if the off-site location is registered with the Board. [20 CSR 2220-2.010(1)(J)]. The following information must be submitted to the Board in writing or via e-mail to register an offsite facility: the storage facility's address, the pharmacy permit number of the pharmacies that will be using the facility, and the facility' hours of operation (if applicable). [20 CSR 2220-2.010(1)(J)] E-mails can be sent to the Board office at: pharmacy@pr.mo.gov (e-mail is preferred).

Off-site record storage locations must meet the following requirements:

- Adequate security must be maintained to guarantee the security and integrity of records, medication, and drug related devices. The off-site location must be equipped with a functional alarm system;
- Security breaches must be reported to the Board within fifteen (15) days; and
- Records stored off-site must be made available for inspection within two business days, if requested. No record less than two years old may be stored off site. [20 CSR 2220-2.010(1)(J)].

Multiple pharmacies may use the same facility, provided each pharmacy registers the facility with the Board as an offsite storage location. Additionally, each pharmacy's records/drug inventory should be individually identifiable and must be securely stored to prevent unauthorized access. Medication stored by a pharmacy at an offsite facility can only be used by the pharmacy for distributing drugs within its own pharmacy operations. Offsite facilities used to distribute medication to multiple pharmacies must be licensed as a

Missouri drug distributor, regardless of pharmacy ownership. [20 CSR 2220-2.010(1)(J)].

Storage and warehouse locations will be considered part of the pharmacy facility and may be inspected by the Board for compliance. *Note: Offsite storage would include storing records at another pharmacy and would require Board registration*. [20 CSR 2220-2.010(1)(J)].

E.15 POLICIES AND PROCEDURES

Effective policies and procedures promote consistency and will help prevent compliance violations. Generally, Missouri law requires the following pharmacy policies and procedures:

Policy/Procedure Type	Regulation	Annual Review Required
General	20 CSR 2220-2.090 (2)(P)	
Class C: Long Term Care	20 CSR 2220-2.140	
Class F: Renal Dialysis	20 CSR 2220-2.600	
Class H: Sterile Products Compounding	20 CSR 2220-2.200	✓
Class I: Consultant in a Residence	20 CSR 2220-2.010 (10)	
Class J: Shared Service	20 CSR 2220-2.650	
Class L: Veterinary	20 CSR 2220-2.675	✓
Class M: Specialty (Bleeding Disorder)	20 CSR 2220-6.100	✓
Classes N & O: Automated Dispensing System	20 CSR 2220-2.900	
Class R: Remote Dispensing Site Pharmacy	20 CSR 2220-2.680(3)	
Class Q: Charitable Pharmacy	20 CSR 2220-2.685(7)	
Administration by Prescription Order	20 CSR 2220-6.040(4)(B)	
Automated Filling Systems	20 CSR 2220-2.950	✓
Drug Take Back	20 CSR 2220-2.095(3)	
Electronic Product Verification	20 CSR 2220-2.011(4)	
Electronic Recordkeeping Systems	20 CSR 2220-2.083	✓
Prescription Deliveries	20 CSR 2220-2.013(1)	
Remote Data Entry Sites	20 CSR 2220-2.725(4)	✓
Technician Duties	20 CSR 2220-2.090(2)(CC)	
Technology Assisted Prescription/ Medication Order Verification	20 CSR 2220-2.012(6)	

Note: Additional policies and procedures may be required by other state/federal law (e.g., DEA, BNDD).

Policies/procedures should be reviewed on a regular basis and updated as needed. Relevant changes should be shared and discussed with pharmacy staff to ensure compliance. Policies and procedures can be maintained electronically but must be readily retrievable during an inspection.

E.16 BOARD REPORTING/NOTIFICATIONS

Pharmacies must notify the Board of the following (*this chart does not include controlled substance reporting requirements*):

WHAT NEEDS TO BE REPORTED?	WHEN?	STATUTE/RULE
Breach of security (Bd. registered offsite warehouse/ storage facility)	Within fifteen (15) days after breach	20 CSR 2220-2.010(1)(I), (J)
Breach of Security (Data processing systems or confidential documents at an offsite location where non-dispensing activities are performed)	Within seven (7) days of the breach	20 CSR 2220-6.055(2)
Breach of Security (Remote Data Entry Site)	Within seven (7) days of the breach	20 CSR 2220-2.725(3)(A)
Change of Classification	Prior to performing new classification activities	§ 338.220
Change of Location	Prior to operating at new location	20 CSR 2220-2.020(4)
Change of Ownership	Prior to operating under new ownership. *Note: Individuals/ Entities acquiring more than 25% of a pharmacy's ownership must notify the Bd. within 30 days*	20 CSR 2220-2.020(1)/20 CSR 2220-2.020(3)(B)
Change of Partners/Members (Pharmacy LLPs or LLCs)	Within ten (10) days after the partnership/membership change	20 CSR 2220-2.020(3)(C)
Compounding Reporting	20 CSR 2220-2.425 (*The Board has delayed enforcement/reporting until January 2024)	20 CSR 2220-2.425 (See I.14)
Dispensing Errors That Reach the Patient (Technology-Assisted Verification Systems)	Within ten (10) days of discovery.	20 CSR 2220-2.012(5)
Final disciplinary action against a technician or a qualifying voluntary resignation (See E.16)	Within fifteen (15) days after action/ resignation	§ 338.013; 20 CSR 2220-2.010(4)
Final adverse action, license surrender or federal exclusion involving or against the pharmacy (See E.16)	Within fifteen (15) days after action/ resignation	§ 338.075; 20 CSR 2220-2.010(4)

Final disciplinary action against a pharmacist employed to provide health care services or a qualifying voluntary resignation (See E.16)	Within fifteen (15) days after action/ resignation	§ 383.133
Intent to provide legend blood-clotting products to bleeding disorder patients (Class-M Pharmacies)	On or before January 31st annually	20 CSR 2220-6.100(3)(A)
Out of Business Notification	Within fifteen (15) days after terminating business	20 CSR 2220-2.015(1)
Pharmacy Remodeling	Remodeling affidavit & project plans filed with Board within thirty (30) days before the change	20 CSR 2220-2.020(4)(A)
PIC Change	Promptly after new PIC is designated	20 CSR 2220-2.010(1)(M)
Recall of a compounded preparation deemed to be misbranded, adulterated or sterile preparations deemed to be non-sterile or if end-preparation testing results are out of specification.	Within three (3) business days after the recall. ***Prescriber notification also required***	20 CSR 2220-2.200(21), 20 CSR 2220-2.400(8)(C)
Sterile Compounding: Any environmental sample as part of a remedial investigation that exceeds USP Chapter 797 action levels	Within three (3) days of detection	20 CSR 2220-2.200(20)(C)
Theft/diversion of or from a collection receptacle used to collect medication for destruction under 20 CSR 2220-2.095	Within fourteen (14) days	20 CSR 2220-2.095(4)(F)
Unauthorized access to a Class R Remote Dispensing Site	Within seven (7) days of discovery	20 CSR 2220-2.680(6)(A)

****Missouri's statewide Prescription Drug Monitoring Program is still being implemented and is not currently operational. However, local/municipal jurisdictions may have a PDMP and mandatory reporting requirements; Check with your local/municipal jurisdiction to ensure compliance. Visit the Missouri PDMP website at https://pdmp.mo.gov/ for additional updates on the statewide PDMP.****

E.17 REPORTING OF DISCIPLINE/ADVERSE ACTIONS

The following disciplinary/adverse actions must be reported to the Board:

TYPE OF ACTION	WHO IS REQUIRED TO REPORT?	WHAT SHOULD BE REPORTED?	WHEN?
Tech. Discipline/ Resignation § 338.013; 20 CSR 2220-2.010(4)	Licensed pharmacies & hospitals	· Any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055 · Any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055	Within fifteen (15) days after action/ resignation.
Pharmacist Discipline/ Resignation § 383.133; 20 CSR 2220-2.010(4)	Any entity that employs a pharmacist to provide health care services (*e.g., pharmacies, hospitals, ambulatory surgical centers, long-term care facilities and nursing homes*)	· Any final disciplinary action against the pharmacist that might have led to disciplinary action under § 338.055 · The voluntary resignation of any pharmacist against whom any complaints or reports have been made which might have led to disciplinary action.	Within fifteen (15) days of the final disciplinary action/ resignation.
Pharmacy Discipline/ Adverse Action § 338.075; 20 CSR 2220-2.010(4)	ALL licensees, registrants and permit holders	· Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacy, drug distributor, drug manufacturer or drug outsourcing facility · Any surrender of a license or authorization to practice as a pharmacy, drug distributor, drug manufacturer or drug outsourcing facility · Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet). *Note: Section 338.075 requires reporting of all disciplinary action or federal exclusions even if the conduct isn't grounds for discipline under § 338.055*	Within fifteen (15) days of action, surrender, or exclusion.

Interested parties should consult legal counsel to determine what actions/voluntary resignations constitute grounds for discipline under § 338.055. In the past, the Missouri Administrative Hearing Commission has found legal grounds for discipline under § 338.055, RSMo, for the following types of conduct:

- *Prescription errors*
- *Practicing without a license*
- *Falsifying prescriptions*
- *Altering a prescription without authorization*
- *Dispensing without a valid prescription*
- *Immunizing without a protocol*
- *Diverting medication*
- *Compounding for office stock*
- *Theft of merchandise, gift cards, food or other items*
- *Violating state/federal controlled substance laws*
- *Unsupervised technicians*
- *Impairment/Illegal drug use*
- *Disciplinary action by BNDD, DEA or another state/ federal agency*

This list is not exhaustive. Additional grounds for discipline exist under § 338.055, RSMo, that are not listed above. *Note: Section 338.075 requires reporting of all disciplinary action or federal exclusions even if the conduct isn't grounds for discipline under § 338.055.*

Notifications/Reports can be filed online at pr.mo.gov/pharmacists-onlineservices.asp or mailed to: Missouri Board of Pharmacy, P.O. Box 625, Jefferson City, Missouri 65102. Online reporting is preferred.

F.1 DISPENSING AUTHORITY

Except as otherwise provided by state or federal law, licensees may only dispense medication pursuant to a "prescription"or "prescription drug order" from an authorized prescriber for a specific patient. [§ 338.095]. Class B pharmacies are also authorized to dispense by medication prescription order (see D.10). A "prescription" or "prescription drug order" isdefined as:

> *A lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient. [§ 338.095].*

F.2 AUTHORIZED PRESCRIBERS

To be valid for dispensing, a prescription must have been written by a prescriber that is licensed in the United States or a U.S. territory who is legally authorized to prescribe. [§ 338.095; 20 CSR 2220-2.020(11)]. Missouri law recognizes the following prescriptive authority:

PRESCRIBER	AUTHORITY
Assistant Physicians	Both controlled & non-controlled prescriptive authority under a collaborative practice agreement with a Missouri licensed physician. *See Section G for Mid-Level Practitioners.*
Advanced Practice Registered Nurses	Both controlled & non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. *See Section G for Mid-Level Practitioners.*
Physicians	Both controlled & non-controlled authority.
Dentists, Veterinarians, Podiatrists and Optometrists	Both controlled & non-controlled authority. May prescribe within their scope of practice.
Physician Assistants	Both controlled & non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. *See Section G for Mid-Level Practitioners.*
Out-of-State Prescribers	Must be legally authorized to prescribe in the prescriber's licensing state/ territory. The prescription may be filled even if similar prescriptive authority is not recognized in Missouri. (e.g., out-of-state chiropractors, pharmacists or psychologists with prescriptive authority).
Non-U.S. Prescribers	Prescriptions from a prescriber licensed in a foreign country or jurisdiction (e.g., Canada, Mexico) cannot be filled unless the practitioner is also licensed and legally authorized to prescribe in a U.S. state or territory. [§ 338.095; 20 CSR 2220-2.020(11)].
Military Prescribers	The Board does not have jurisdiction over pharmacy practice on military bases. Prescriptions from a member of the armed forces may be filled by a Missouri pharmacy if the prescription complies with federal requirements.

Licensees are responsible for ensuring valid prescriptive authority and, if applicable, proper controlled substance authority. The DEA publishes a state listing of authorized controlled substance prescribers at www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. The National Association of Boards of Pharmacy (NABP) also publishes a state-specific listing in its Annual Survey of Pharmacy Law that can be purchased at https://nabp.pharmacy/resources/publications/. *Note: These resources are not maintained by the Board and the Board cannot guarantee their accuracy.*

Self-Prescribing: Physicians cannot prescribe controlled substances for themselves unless it is a medical emergency (see § 195.070.5, RSMo). Physicians may prescribe non-controlled drugs for themselves, however, the practice is discouraged by the Board of Healing Arts.

Family Members: Physicians may prescribe controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as he/she would for any other patient and all other prescription requirements are met. Please consult the Board of Healing Arts for additional guidance.

Inactive Physicians: The Board has confirmed with the Missouri Board of Healing Arts that physicians with a valid inactive Missouri physician license are authorized to prescribe non-controlled medication for themselves or immediate family members, as referenced in § 334.002 which provides:

> 1. Notwithstanding any law to the contrary, any person licensed pursuant to this chapter may apply to the state board of registration for the healing arts for an inactive license status on a form furnished by the board. Upon receipt of the completed inactive status application form and the board's determination that the licensee meets the requirements established by rule, the board shall declare the licensee inactive and shall place the licensee on an inactive status list. *A person whose license is inactive or who has discontinued his or her practice because of retirement shall not practice his or her profession within this state, but shall be allowed to practice his or her profession on himself or herself or on his or her immediate family, however, such person shall not be allowed to prescribe controlled substances.* Such person may continue to use the title of his or her profession or the initials of his or her profession after such person's name.

F.3 PRESCRIPTION FORMAT

Prescriptions from a Missouri prescriber no longer have to be in two-line format (e.g., two signature lines on opposite ends of the bottom of the prescription). However, two-line prescriptions may still be filled if otherwise valid. Prescriptions from non-Missouri prescribers must be in the format approved in the state/territory where the practitioner is licensed. *See H.11 for Generic Substitution.*

Security Paper: Paper prescriptions with an electronic signature must be applied to security paper that will detect or identify if the prescription/medication order has been copied or altered (e.g., watermark, microprint, heat detection/rub features). [20 CSR 2220-2.085]. Paper or computer generated prescriptions that are physically signed by the prescriber do not need to be on security paper. BNDD has confirmed that security paper is strongly recommended but not required for controlled substance prescriptions. *Note: CMS may require tamper resistant paper for Medicaid reimbursement.*

F.4 PRESCRIPTION REQUIREMENTS

To be valid for dispensing, prescriptions must include:

1) The date of prescribing;
2) The name of the patient(s), or if an animal, species and owner's name;
3) A written signature or valid electronic signature that complies with 20 CSR 2220-2.085. For verbal prescriptions, the prescriber's name must be documented;
4) Name, strength & dosage of the drug, device or poison prescribed and the directions for use;
5) The number of refills, if applicable;
6) The quantity prescribed in weight, volume, or number of units;
7) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail, including, but not limited to, a change in quantity, directions, number of refills, or substitution authority; and
8) Prescriptions from a Missouri mid-level practitioner must include the name, telephone number and address of both the physician and the prescribing mid-level practitioner [Physician Assistants: § 334.735.4(3), (Assistant Physicians: 20 CSR 2150-2.240(2)(E)7.; Advanced Practice Registered Nurses: 20 CSR 2150-5.100(2)(G)7.] *See Section G for Mid-Level Practitioners.*

Controlled substance prescriptions must also include:

- The address of the prescriber and the patient
- The dosage form
- The prescriber's Drug Enforcement Administration (DEA) number, and
- Any other information required by state/federal law. [See 20 CSR 2220-2.018]

Prescriptions must be consecutively numbered or assigned a unique, readily retrievable identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017]. The Board anticipates further defining a "unique identifier" by rule. In the interim, prescriptions should be uniquely labeled in a manner that allows individual retrieval.

F.5 PRESCRIPTION CHANGES

Changes to prescriptions or medication orders may only be communicated by the prescriber or the prescriber's duly authorized representative. Once received, authorized changes should be documented on the prescription or in the pharmacy's prescription records.

The Board has been advised the DEA is reviewing/revising authorized changes for C-II controlled substance prescriptions. Pending further DEA guidance, BNDD issued the following guidance in August 23, 2022, for schedule II controlled substances:

(BNDD and DEA guidance/rules may have changed since the printing of this Practice Guide. See BNDD's or DEA's websites/rules for current guidance.)

Methods of changing C-II controlled substance prescriptions:

1. A prescriber may provide a change to the pharmacy that the pharmacy must attach to the original prescription. The written change shall document the date and name of the person authorizing the change. The change may be electronic, mailed, emailed, or faxed.
2. The change may be communicated orally. The pharmacy shall record the date, changes, and person authorizing the changes on the front or back of the prescription. This may happen if the prescriber has a waiver from the mandated electronic prescribing.

What may be changed/added on a controlled substance changed/added prescription with permission	What CAN NEVER be
• Date written • Patient's address (complete physical address, not P.O. Box) • Drug form • Drug strength • Quantity to be dispensed • Prescriber's address • Prescriber's DEA number • Directions for use • Substitutions permitted • Refill information • Reasons for extended supplies for Schedule II prescriptions.	• Patient's name • Drug name • Prescriber's name • Prescriber's signature

According to BNDD, "BNDD does not consider it a change to the prescription if the pharmacy documents dispensing notes and information on a prescription. These are notes such as adding an NPI number, or determining morphine equivalents (MME), or adding a phone number." See BNDD 8-23-22 Guidance at: https://health.mo.gov/safety/bndd/pdf/changes-to-scripts-8232022.pdf

F.6 PATIENT-PRACTITIONER RELATIONSHIP

Prescriptions must be based on a valid patient-practitioner relationship. [20 CSR 2220-2.020(11)]. Additionally, the practitioner must have performed a valid medical evaluation, as required by law. [20 CSR 2220-2.020(11)]. A prescription may not be filled if the pharmacist knows, or should reasonably know under the circumstances, that the prescription was based solely on an internet-based questionnaire. [20 CSR 2220-2.020(11)]. See F.14 for Telehealth/Telemedicine.

If the pharmacist knows or has reason to believe the patient is not under the prescriber's care at the time the prescription is presented, the pharmacist is required to consult with the prescriber to determine if the prescriber intends for the medication to be dispensed. Confirmation should be documented in the prescription record.

Retired, Deceased, or Disciplined Prescribers: Missouri law does not definitively address filling/refilling of prescriptions that were validly written before a prescriber passes away, stops practicing or is disciplined. Except as otherwise provided by law, pharmacists may dispense an otherwise valid prescription that was lawful when it was originally written. However, pharmacists should use their professional judgment when dispensing additional refills and should advise patients to consult with another practitioner as soon as possible. Contact BNDD for guidance on dispensing controlled substances. See section H.17 for emergency dispensing options.

Inactive Physicians: The Board has confirmed with the Missouri Board of Healing Arts that physicians with a valid inactive Missouri physician license are authorized to prescribe non-controlled medication for themselves or immediate family members, as referenced in § 334.002 which provides:

1. Notwithstanding any law to the contrary, any person licensed pursuant to this chapter may apply to

the state board of registration for the healing arts for an inactive license status on a form furnished by the board. Upon receipt of the completed inactive status application form and the board's determination that the licensee meets the requirements established by rule, the board shall declare the licensee inactive and shall place the licensee on an inactive status list. *A person whose license is inactive or who has discontinued his or her practice because of retirement shall not practice his or her profession within this state, but shall be allowed to practice his or her profession on himself or herself or on his or her immediate family, however, such person shall not be allowed to prescribe controlled substances.* Such person may continue to use the title of his or her profession or the initials of his or her profession after such person's name.

F.7 AUTHORIZED SIGNATURES

Prescriptions must be signed by the prescriber as authorized by law. [§ 338.056]. The following signatures are currently allowed:

	Non-Controlled Substances (Paper, Faxed, Scanned or Electronic)	Controlled Substances (Paper, Faxed)	Controlled Substances (Electronic/ E-Prescribed)
Manual Signature	✓	✓	X
Electronic Signature	✓	X	✓
Stamped Signature	X	X	X

The prescriber's staff/agent may prepare the prescription, however, the prescriber must manually or electronically sign the prescription before it is issued.With the exception of Schedule II controlled substances, licensees may obtain a verbal prescription if the prescriber's signature is invalid.

- Manual Signatures: Prescribers may manually sign a prescription in the same manner used for signing a check orother legal document. Rubber-stamped signatures are not valid.
- Electronic Signatures (Non-Controlleds): If signed electronically, the prescriber's electronic signature must be either an exact electronic replica of the prescriber's signature or a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD"). [20 CSR 2220-2.085] Paper prescriptions that are electronically signed must be applied to secure paper that will detect or identify if the prescription has been copied or altered (see F.3).
- Controlled Substances: Controlled substance prescriptions must comply with state/federal law. Generally, all paper and faxed controlled substance prescriptions must be manually signed by the prescriber. According to BNDD, digitally scanned signatures are not acceptable. Electronic controlled substance prescriptions must comply with all DEA and BNDD electronic prescribing requirements.

F.8 PRESCRIPTION LIMITS

The following Missouri prescription limits generally apply (controlled substance guidance provided by BNDD): *See Section G for other Mid-Level Practitioner Requirements*

	Non-Controlleds	Schedule II Controlled Substances	Schedule III-IV Controlled Substances	Schedule V Controlled Substances
Prescription Validity	One (1) year	Six (6) Months	Six (6) Months	One (1) year
Quantity Limits	As prescribed	30-Days/ 90-Days with documented medical reason	90-Days	90-Days
Refills	As prescribed	May not be refilled	Up to five (5) refills within six (6) months	As prescribed

According to BNDD, out-of-state prescribers may prescribe controlled substances according to the authority of their home state (including Mid-Level Practitioners). When prescribed by an out-of-state prescriber, the above controlled substance quantity limits apply if the patient is a Missouri patient. If the patient is an out-of-state patient, the quantity limits of the prescriber's home state apply. [See § 195.080]

Initial Opioid Prescription Limits for the Treatment of Acute Pain:

(The highlighted information below has been provided by BNDD. BNDD rules/guidance may have changed since the printing of the Practice Guide; See BNDD's website for current rules/guidance).

An initial prescription for a drug is defined in the law as when the patient has not previously received that drug during the past five (5) months. Acute pain is the pain that is expected to last only a short period of time and does not include chronic pain, cancer-related pain, hospice or other end-of-life care [see § 195.010(1)]. When treating acute pain, and the patient has not received the opiate drug in the past 5 months, the prescriber is restricted to a 7-day supply. [See § 195.080] If needed, the prescriber can issue a new and second prescription for additional doses, after a subsequent consultation. This 7-day restriction is for the treatment of acute pain and does not apply to treatment that is not for pain such as codeine for coughing or diphenoxylate for IBS. This law applies to Missouri prescribers but not prescribers from outside of Missouri.

What Are the Exemptions and Exceptions to This 7-Day Limit?

1. Patients currently undergoing treatment for cancer;
2. Patients enrolled in hospice or receiving palliative care;
3. Patients who are residents in a licensed long-term care facility;
4. Patients receiving buprenorphine for the treatment of substance abuse;
5. The 7-day limit law does not apply to out-of-state prescribers;
6. The 7-day limit law does not apply to Missouri veterinarians;
7. If in the professional medical judgment of the practitioner, they determine that more than a 7-day supply is required to treat the patient's acute pain, the practitioner may issue a prescription for the

quantity needed to treat the patient's acute pain; provided that the practitioner shall document in the patient's medical record the condition triggering necessity for more than a 7-day supply and that a non-opioid alternative was not appropriate to address the patient's condition. **In these cases, it is extremely important that the prescriber documents similar information on the prescription so that a pharmacy would know and understand the reason for the greater supply.**

What if the Prescriber Issues a Prescription for a Prescription That Exceeds Seven Days?
A prescriber may only exceed the initial 7-day prescribing limit if there is a qualifying exception as listed in the paragraph above. The pharmacy may dispense a 7-day supply and the remainder of the prescription shall be void. The law requires a second prescriber-patient consultation before another opiate prescription is authorized.

(See BNDD's Controlled Substance Guidelines for Missouri Pharmacies for additional information)

C-II Partial Fills:

(The following information has been provided by BNDD. BNDD rules/guidance may have changed since the printing of the Practice Guide; See BNDD's website for current requirements/guidance)

(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and s/he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription. *(A partial dispensing of drugs is not counted as an entire refill)*

(2) The partial filling of a prescription for controlled substances listed in Schedules II, III, IV, or V is permissible, provided that:

(A) Partial filling may occur at the request of a patient or it may be directed by the prescriber;
(B) Each partial dispensing is recorded in the same manner as a refilling would be;
(C) With each partial dispensing, the pharmacy must document the date and quantity dispensed on the original prescription record or their approved electronic computer applications, provided that the electronic system meets all of the federal requirements for handling of electronic prescriptions for controlled substances, including the ability to retrieve the information pertaining to partially filled controlled substances; *(A partial dispensing does not count as an entire refill)*
(D) The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed;
(E) No dispensing occurs after six (6) months after the date on which the original prescription was issued;
(F) A partial dispensing is not considered a "refill" if the patient does not receive the full authorized amount at one time; and
(G) The prescription was written and filled in accordance with all other applicable laws and regulations.

See BNDD rule *19 CSR 30-1.064* for additional partial fill requirements/allowances. Questions regarding C-II partial fills should be addressed to BNDD.

F.9 CORRESPONDING RESPONSIBILITY

Controlled substance dispensing is regulated by the U.S. Drug Enforcement Administration (DEA) and the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD). Under federal law, pharmacists have a corresponding responsibility for the proper dispensing of controlled substances.

The DEA issued the following guidance in the 2022 DEA Pharmacist Manual:

> *A pharmacist has a corresponding responsibility for the proper dispensing of controlled substances. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 U.S.C. 841(a)(1), 21 U.S.C. 842(a)(1), and 21 CFR 1306.04(a).*
>
> *A pharmacist is required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription. 21 CFR 1306.04(a) and 1306.06. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. United States v. Veal, 23 F.3d 985 (6th Cir.1994). Such action is a felony offense, which upon conviction, may result in a term of imprisonment and a fine. 21 U.S.C. 841(b). Unlawful dispensing of controlled substances by a pharmacist may also be subject to criminal actions against the pharmacy or pharmacist, and to civil enforcement actions against the pharmacy or pharmacist for money penalties or injunctions. 21 U.S.C. 842 and 843. Moreover, DEA may revoke a pharmacy's registration based on a finding that its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of proceedings against their state licenses. Jones Total Healthcare, L.L.C., v. DEA, 881 F.3d 823 (11th Cir. 2018).*

The Board also recommends the following resources on "red flags" that may help identify fraudulent prescriptions:

- DEA "A Pharmacist's Guide to Prescription Fraud" (DEA Pharmacist Manual- Appendix D)
- BNDD's "Preventing Prescription Fraud" Guide

F.10 VERBAL/TELEPHONE PRESCRIPTIONS

Pharmacists may accept a verbal or telephone prescription communicated by the prescriber or the prescriber's duly authorized agent. Verbal/telephone prescriptions must be promptly reduced to writing or electronically recorded in the pharmacy's prescription records. [§ 338.095]. All prescription information required by 20 CSR 2220-2.018 must be recorded, including, if substitution is permitted. [§ 338.056.4]

- Non-Controlled Substance Transfers: Non-controlled prescriptions may be verbally received/transferred by a pharmacist or a technician/intern pharmacist acting under the pharmacist's direct supervision.
- Controlled Substance Transfers: Controlled substance prescription transfers may only be communicated between two pharmacists. Pharmacy technicians and intern pharmacists may not provide or receive controlled substance transfers. (See F.13)

F.11 FAXED/SCANNED PRESCRIPTIONS

Faxed/scanned prescriptions are defined as an "electronic image transmission" under 20 CSR 2220-2.085 and may be filled by a pharmacy provided the faxed/scanned prescription includes all prescription information required by § 338.056 and 20 CSR 2220-2.018 and meets all other prescription requirements.

Pharmacists should use their professional judgment and take appropriate measures to verify the authenticity of a faxed/scanned prescription. Faxed/scanned prescriptions may only be sent by the prescriber or the prescriber's authorized agent. Pharmacies cannot fill prescriptions faxed or scanned by a patient.

Authorized Signatures:

- Non-Controlled Substances: Faxed/scanned non-controlled prescriptions may be manually or electronically signed as authorized by 20 CSR 2220-2.085. See section F.7 for signature requirements)
- Controlled Substances: Faxed controlled substance prescriptions have to be physically signed by the prescriber and must comply with all BNDD and DEA requirements. The DEA does not allow an electronically signed controlled substance prescription that is generated from a prescriber's software to be converted to fax. See 20 CSR 2220-2.085 and F.12 for additional electronic prescription requirements.

F.12 ELECTRONIC PRESCRIPTIONS

Non-Controlled Substance Prescriptions: Prescriptions for non-controlled drugs may be transmitted electronically by the prescriber or the prescriber's authorized agent either as an "electronic image transmission" or an "electronic prescription."

- An "electronic image transmission" is an exact visual image of a physical prescription that is then faxed, scanned or sent to the pharmacy in an electronic format. Electronic image transmissions must be manually or electronically signed (See F.7)
- An "electronic prescription" is any prescription/medication order other than an "electronic image transmission" that is electronically transmitted to the pharmacy by the prescriber or the prescriber's authorized agent. [20 CSR 2220-2.085(1)]. Electronic prescriptions may be signed using an electronic signature that is either an exact electronic replica of the prescriber's signature or a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD"). [20 CSR 2220-2.085] Electronic prescriptions must be sent by the prescriber or the prescriber's authorized agent. Prescriptions sent electronically by the patient are not valid for dispensing.

Controlled Substances:

Non-Missouri Prescribers: According to BNDD, e-prescribing of controlled substances is permitted if the pharmacy and prescriber use software that has been certified to meet DEA requirements and comply with all DEA electronic prescribing requirements (additional requirements may apply in the pharmacy's home state).

Missouri Prescribers: Section 195.550, RSMo, requires that prescriptions for Schedule II, III, and IV controlled substances from a Missouri prescriber must be prescribed electronically unless the prescription falls under a statutory exception or the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) has

issued a prescriber waiver. E-prescribing must comply with all DEA and BNDD requirements (see BNDD rules 19 CSR 30-1.048(9) and 19 CSR 30-1.062(4)). However, § 195.550.5 provides:

> A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. ***Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with state and federal laws and regulations*** *(emphasis added).*

Licensees may continue to dispense otherwise valid written, oral or faxed controlled substance prescriptions as authorized by § 195.550, unless directed otherwise by the BNDD/DEA. (See BNDD's website for additional e-prescribing guidance.)

F.13 PRESCRIPTION TRANSFERS (ORIGINALS & REFILLS)

Upon request, a prescription/medication order may be transferred if:

- The prescription/medication and or refills were authorized by the prescriber;
- The prescription/medication order hasn't exceeded the maximum allowable time limit; and
- The number of lawfully allowable refills has not been exceeded (if applicable) [20 CSR 2220-2.120].

Transfer requests received directly from the patient or the patient's caregiver must be transferred within one (1) business day of the request. [20 CSR 2220-2.120(5)]. The Board amended 20 CSR 2220-2.120(5) in 2021 to provide transfer requests that are not received directly from the patient or the patient's caregiver must be completed in a timely manner, provided licensees/permit holders must ensure that no interruption in patient therapy will occur if the prescription is not transferred within one (1) business day. [20 CSR 2220-2.120(5)]

The rule amendment was intended to allow licensees to use their professional judgment, and should not be abused. Collaboration is key here. The pharmacy requesting the transfer should communicate any urgent need when requesting a transfer. Similarly, the Board recommends that the transferring pharmacy communicate if a transfer may have additional delays.

Licensees will be asked to explain/substantiate any transfer that is not completed in a timely manner. Transfer requests received directly from the patient or the patient's caregiver must still be transferred within one (1) business day, without exception.

Prescriptions may only be transferred to or from a pharmacy licensed in a U.S. state/territory [20 CSR 2220-2.120(1)]. Prescriptions may not be transferred to an unlicensed entity or to a pharmacy that is not located in a U.S. state/territory.

The transferring and receiving pharmacy must record:

TRANSFERRING PHARMACY	RECEIVING PHARMACY
· The name and the location of the pharmacy where the prescription/medication order was transferred (e.g., address); · The transfer date; · The identity of the individuals transferring and receiving information (e.g., the pharmacist, pharmacy technician or intern pharmacist doing the transfer). **Not required if the transferring/receiving pharmacies are under the same ownership and share the same electronic database;* · For controlled substances, the receiving pharmacy's DEA number and the full name of the pharmacists transferring and receiving the prescription information; and · The prescription/medication order must be immediately voided in the pharmacy's electronic system or the word "void" must be written on the face of the invalidated prescription. (see exception below for Class-C Long Term Care pharmacies).	· An indication that the prescription/medication order was transferred; · The date the Rx/medication order was originally issued; · The date the prescription/medication order was first dispensed;* · The number of refills originally authorized and the number of remaining refills; · Date of last refill;* · The prescription number or other unique identifier;* · The name and location of the pharmacy that transferred the prescription/medication order; · The identity of the individuals transferring and receiving the information (not required if the transferring/receiving pharmacies are under the same ownership and share the same electronic database), and; · For controlled substances, the address and DEA # number of the transferring pharmacy and the full names of the pharmacists transferring and receiving the prescription/ medication order; and · All other required information for an original prescription/ medication order. * Not required for original prescription transfers.

If a prescription/medication order is transferred using an electronic data processing record-keeping system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the pharmacy, the prescription must be treated as a new record, showing the original date issued and original expiration date [20 CSR 2220-2.080(9)].

The Board is aware of pharmacies improperly denying transfers due to pharmacy disputes, unpaid patient accounts/bills or early refills. Legally valid transfer requests are mandatory. If the refill is too soon, the transferring pharmacy may call attention to the early refill but ***cannot*** *refuse to transfer. The receiving pharmacy is responsible for reviewing the prescription before dispensing to prevent unauthorized refills.*

Long-Term Care:

20 CSR 2220-2.120 allows Class-C pharmacies to transfer up to a seventy-two (72) hour supply of a non-controlled prescription/medication order to a second pharmacy for initial dispensing without voiding the remaining prescription. The amount transferred must be deducted from the remaining prescription/medication order but the prescription at the transferring pharmacy no longer has to be voided [20 CSR 2220-2.120(4)]. A Class-J Shared Services permit is not required for the transfer. [20 CSR 2220-

2.650(3)]

Nursing home orders are not transferable if the patient is discharged from the facility. Additionally, refills associated with a nursing home order are not valid for use outside of the facility under 20 CSR 2220-2.140(5)(D).

Controlled Substances:

Transfer of a controlled substance prescription/medication order must comply with 20 CSR 2220-2.120 and all applicable state and federal controlled substance laws. Controlled substance prescriptions/medication orders may only be transferred one (1) time, however, pharmacies electronically sharing a real-time database may transfer a controlled substance up to the maximum refills allowed by law and authorized by the prescriber. [20 CSR 2220-2.120(1)(E)]

TRANSFER OF CONTROLLED SUBSTANCES PRESCRIPTION INFORMATION FOR INITIAL DISPENSING

The Board continues to receive questions on when an unfilled new controlled substance prescription may be transferred from one pharmacy to another pharmacy for initial dispensing. The information below is our understanding of current DEA guidance as it relates to DEA-registered retail pharmacies: (this information is current as of October 2022; Licensees should check with DEA and BNDD to ensure compliance with current law)

TYPE OF CONTROLLED SUBSTANCE PRESCRIPTION	MAY BE TRANSFERRED	MAY BE FORWARDED
WRITTEN	NO	NO
FAXED	NO	NO
VERBAL	NO	NO
ELECTRONIC (EPCS)	NO	YES**

***The DEA has advised that electronic prescriptions may only be forwarded using a DEA compliant electronic prescription system (EPCS).*

F.14 TELEHEALTH/TELEMEDICINE

Section 191.1145 allows a Missouri licensed healthcare provider to provide "telehealth" or "telemedicine" services which are defined as:

The delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self management of a patient's health care while such patient is at the originating site and the health care provider is at the distant site. Telehealth or telemedicine shall also include the use of asynchronous store-and-forward technology.

A Missouri pharmacy may fill a prescription that is issued based on a valid "telehealth" or "telemedicine" exam. To be valid, a telemedicine prescription from a Missouri prescriber must meet the following requirements:

- The prescriber must be licensed to practice in Missouri, and

- The prescription must be based on a valid prescriber-patient relationship, and
- The prescription must comply with all other state/federal prescription requirements, including, 20 CSR 2220-2.018, § 338.056 and any applicable controlled substance laws, and
- The telemedicine services must be within the provider's "scope of practice" and meet the applicable standard of care. [§ 191.1145, § 191.1146]

A telemedicine prescription CANNOT be filled if:

- No legitimate practitioner-patient relationship exists, or
- The prescription was issued based solely on an internet request or an internet questionnaire, or
- The prescription was based solely on a telephone evaluation without a previously established and ongoing prescriber-patient relationship. [§ 191.1146, § 334.108.(3) – (.4)]

Pharmacists should use their professional judgment to determine if a valid prescriber-patient relationship exists. Determining the applicable standard of care will depend on the health care provider's licensing regulations and applicable medical standards. The Board cannot give additional guidance here. However, licensees should be attentive to prescriptions that appear to be outside of the prescriber's scope of practice.

> *The Board is aware that prescribers frequently issue prescriptions after consulting with a patient over the phone. A prescription may be issued based on a telephone evaluation if "a previously ongoing physician-patient relationship exists" between the prescriber and the patient being treated. [Sec. 334.108.3]. This exception would allow prescribers to continue their current practice of consulting with patients over the phone if the provider and patient have a previously established, ongoing relationship.*

Mid-Level Practitioners: Missouri's telehealth/telemedicine provisions are applicable to prescriptions issued by "any licensed health care provider" which would include APRNs, assistant physicians and physician assistants acting within their licensed scope of practice. However, mid-level practitioners must comply with all applicable prescribing and collaborative practice requirements.

Controlled Substances: The Ryan Haight Act and federal controlled substance laws include specific requirements for telemedicine and controlled substances. Licensees should consult with legal counsel, the DEA and BNDD to ensure compliance with applicable federal law. The Board cannot give legal advice. However, the DEA has issued the following caution:

> *[T]he pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. United States v. Veal, 23 F.3d 985 (6th Cir.1994). Such action is a felony offense, which upon conviction, may result in a term of imprisonment and a fine. 21 U.S.C. 841(b).*

BNDD has also issued the following excerpted statement regarding telemedicine and controlled substance activities:

The Missouri BNDD has reviewed the telemedicine statutes and discussed them with the Drug Enforcement Administration (DEA). The statutes provide definitions and make determinations on the delivery of telemedicine. As always, a state licensing board would make determinations regarding proper clinical care. For controlled substance prescribing and dispensing, the following issues are relevant:

- *The controlled substance activity must be by an authorized and registered professional who is acting within their scope of professional practice and within the guidelines of Chapter 195, RSMo and its regulations.*
- *For Missouri practitioners who will be prescribing, the prescribers must have a professional Missouri*

license, a Missouri BNDD registration and a Missouri DEA registration. This registration must be at their primary practice location where they spend the most time.

- *According to the DEA, pursuant to 21 USC 802(54), if the telemedicine is taking place across state lines, the prescriber must be licensed and also have DEA registrations in both states; the state they are prescribing from and also the state where the patient is. If the patient is an in-patient admitted to a hospital, the hospital may have one of their local practitioners issue the drug orders or the hospital may allow that out of state consulting physician to use the hospital's DEA number pursuant to 21 CFR 1301.22(c).*

Pharmacists play a vital role in preventing prescription fraud and abuse. Licensees are reminded of their corresponding responsibility and should exercise sound professional judgment when determining if a telehealth/telemedicine prescription is legitimate (see F.9 Corresponding Responsibility for additional information/resources).

Out-of-State Prescribers: The Missouri Board of Registration for the Healing Arts has not issued additional guidance on the applicability of Missouri's telehealth/telemedicine provisions to out-of-state prescribers. Licensees are reminded that Board rule 20 CSR 2220-2.020(11) provides:

> *A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid preexisting patient-practitioner relationship.*

Prescriptions based solely on an internet-based questionnaire or that are issued without a valid pre-existing patient-practitioner relationship are not valid in Missouri and cannot be filled, regardless of the location of the prescriber.

G.1 AUTHORIZED MISSOURI MID-LEVEL PRACTITIONERS

Chapter 334, RSMo, authorizes the following mid-level practitioners to prescribe both controlled and non-controlled substances under a collaborative practice agreement with a Missouri licensed physician:

- Advanced Practice Registered Nurses (APRN) [§ 334.104]
- Assistant Physicians (AP) [§ 334.037] ; and
- Physician Assistants (PA) [§ 334.747].

Assistant Physicians (AP) are different from Physician Assistants (PA). Assistant Physicians are recent medical school graduates who have not yet entered a residency program. Physician Assistants have medical training but do not have to be medicalschool graduates.

To prescribe controlled substances, an authorized Missouri mid-level practitioner must have a current BNDD and DEA registration. Mid- level practitioners cannot independently purchase, stock, dispense or administer controlled substances without a collaborative practice agreement with a Missouri licensed physician. *See G.4 for Non-Resident Mid-Level Practitioners.*

G.2 PRESCRIPTION REQUIREMENTS

To be valid for dispensing, prescriptions from a Missouri mid-level practitioner must include:

1. The date of prescribing;
2. The name of the patient(s), or if an animal, the species and owner's name;
3. The name, telephone number and address of the mid-level practitioner and the supervising/collaborating physician. For verbal prescriptions, the name of the mid-level practitioner must be documented;
4. For written prescriptions, the mid-level practitioner's manual signature or valid electronic signature as authorized by 20 CSR 2220-2.085 (*the supervising physician's signature is not required)*;
5. Name, strength and dosage of drug, device or poison prescribed and the directions for use;
6. The number of refills, if applicable;
7. The quantity prescribed in weight, volume, or number of units;
8. For controlled substances, prescriptions must comply with all state and federal controlled substance laws and include the patient's address, the mid-level practitioner's address, and the mid-level practitioner's DEA number. The collaborating physician's DEA number is not required.
9. Any other change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail, including, but not limited to, a change in quantity, directions, number of refills, or substitution authority. [See 20 CSR 2220-2.018, § 334.735.4 (Physician Assistants), 20 CSR 2150-2.240 (Assistant Physicians) and 20 CSR 2200-4.200(3)(G).7 (APRNs)].

Except as otherwise provided by law, prescriptions from mid-level practitioners must be based on a valid patient-practitioner relationship and must comply with all other prescription requirements applicable to physicians. [See Section F]

G.3 REFILLS/QUANTITY LIMITS

The following refills/quantity limits are authorized for a Missouri mid-level practitioner (controlled substance guidance provided by BNDD):

The physician may limit authorized refills/quantity limits in the governing collaborative practice agreement. If limited, the collaborative practice agreement will control.

	Missouri Advanced Practice Registered Nurse	Missouri Assistant Physicians/ Physician Assistants
Non-Controlled Prescriptions	· Valid for 1 year · Refills/quantity limits as prescribed	· Valid for 1 year · Refills/quantity limits as prescribed
Schedule II	· Hydrocodone products only (includes single ingredient products) · Limited to a 5-day or 120-hour supply	· Hydrocodone products only (includes single ingredient products) · Limited to a 5-day or 120-hour supply
Schedule III (Opiates)	· Limited to a 5-day or 120-hour supply · Prescription valid for 6-months from date issued. · No refills allowed***	· Limited to a 5-day or 120-hour supply · Prescription valid for 6-months from date issued · No refills allowed***
Schedule III (Non-Opiates)	· Full authority to prescribe · 90-Day quantity limits · Prescription valid for 6-months from date issued.	· Limited to a 5-day or 120-hour supply · Prescription valid for 6-months from date issued. · No refills allowed
Schedule IV & V	· Full authority to prescribe · 90-day supply limit for a single prescription · C-IV: Prescription valid for 6-months from date issued · C-V: Prescription valid for 12-months from date issued.	· Full authority to prescribe · 90-day supply limit for a single prescription · C-IV: Prescription valid for 6-months from date issued · C-V: Prescription valid for 12-months from date issued.
Buprenorphine	· Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. · Must meet federal requirements & have an "X" DEA number. · No refills allowed***	· Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. · Must meet federal requirements & have an "X" DEA number. · No refills allowed***
Family Members (Controlled Substances)	No authority; Cannot prescribe controlled substances for family members as defined below [§195.070]	No authority; Cannot prescribe controlled substances for family members as defined below. [§ 334.037.12; § 334.747]
Self-Prescribing (Controlled Substances)	No authority; Cannot prescribe controlled substances for themselves	No authority; Cannot prescribe controlled substances for themselves [§ 334.037.12; § 334.747]

**** According to BNDD, a new prescription can be written for an additional 5-day supply (30-days for buprenorphine), however, a new prescription and prescription number would have to be generated. BNDD*

would consider these new prescriptions and not refills.

"Family" is defined by the state's medical board as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law (adopted and step members are included). [20 CSR 2150-5.100(3)(G)(10)].

See F.8 for initial opioid prescription limits for the treatment of acute pain.

MID-LEVEL PRACTITIONER CONTROLLED SUBSTANCE STATUTES/RULES

- APRN: § 195.070; 20 CSR 2150-5.100
- Assistant Physicians: [§ 334.037; 20 CSR 2150-2.240]
- Physician Assistants: [§ 334.747; 20 CSR 2150-7.135]

G.4 NON-RESIDENT MID-LEVEL PRACTITIONERS

Prescriptions from non-resident mid-level practitioners may be filled in Missouri if the prescription is valid in the prescriber's home state. The following refills/quantity limits apply unless otherwise restricted by the prescriber'shome state (*controlled substance guidance provided by BNDD*):

Out-of-State Midlevel Practitioner	
Non-Controlled Prescriptions	· As authorized by the prescriber's home state
Schedule II	· Rx valid for 6-months from date issued · No refills Supply limit: · MO patient: 30-Day supply/ 90-Day supply with documented medical reason · Non-MO patient: As allowed in home state
Schedule III (Opiates & Non-Opiates)	· Rx valid for 6-months from date issued · Refills as allowed in home state. Supply limit: · MO patient: 90-Day supply · Non-MO patient: As allowed by home state.
Schedule IV & V	· C-IV prescription valid for 6-months from date issued · C-V prescription valid for 12-months from date issued · Refills as allowed in home state. Supply limit: · MO patient: 90-Day supply. · Non-MO patient: As allowed in home state.
Family Members	· As allowed by home state
Self-Prescribing	· As allowed by home state

Prescriptions from a non-resident mid-level practitioner may be filled even if similar prescriptive authority is not recognized in Missouri for the same mid-level practitioner (e.g., a non-resident chiropractor).

The DEA publishes a state listing of mid-level practitioners authorized to prescribe controlled substances online at https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. *Note: This resource is not maintained by the Board and the Board cannot guarantee its accuracy.*

H.1 GENERAL REQUIREMENTS

Medication and drug-related devices must be properly and accurately prepared, labeled, and dispensed under clean, and when required, aseptic conditions. [20 CSR 2220-2.010(1)(I)] Licensees may dispense medication pursuant to a valid patient-specific prescription or prescription drug order from an authorized prescriber. Class-B Hospital pharmacies may also dispense pursuant to a medication order.

To ensure sanitation, staff must wear disposable gloves when physically touching individual dosage units. [20 CSR 2220-2.010(1)(I)] As identified in section E.5, outdated, distressed, misbranded or adulterated drugs and drugs for personal employee use must be quarantined in a clearly marked area that is physically separated from the active inventory. [20 CSR 2220-2.010(2)(B)]. The Board defines "misbranded" and "adulteration" consistent with state and federal law, including, but not limited to, Sections 501 and 502 of the Food, Drug and Cosmetic Act [21 USC § 351, § 352], § 196.095 and § 196.100, RSMo.

> *Reheating/Resealing: The Board has received questions regarding sealing/resealing drugs more than once in the type of packaging where intense heat is utilized to seal the packaging (e.g., blister cards). USP discourages the practice because the effect of reheating on the medication is unknown. As noted by USP, several manufacturers also recommend against heat sealing drugs more than once. In accordance with USP, the Board discourages the practice.*

H.2 DATA ENTRY

Pharmacy technicians and intern pharmacists may perform prescription data entry activities at the pharmacy or from a remote data entry site that complies with 20 CSR 2220-2.725 (see H.3 for remote data entry). Prescription/medication order data entered by a pharmacy technician/intern pharmacist must be verified by a pharmacist for accuracy before dispensing, regardless of where data entry occurs. [20 CSR 2220-2.080(1)] The identity of the verifying pharmacist must be documented in the pharmacy's electronic data processing system (e.g., initials, unique code). [20 CSR 2220-2.017(1)(L); 20 CSR 2220-2.080(2)(L)].

H.3 REMOTE DATA ENTRY

20 CSR 2220-2.725 allows pharmacy technicians and intern pharmacists to perform data entry activities at a remote data entry site that is outside of a pharmacy (e.g., from home). A remote data site is defined as:

> *A remote site located in a U.S. state or territory that is operated by a Missouri licensed pharmacy and used by a registered pharmacy technician or intern pharmacist to electronically perform non-dispensing data entry functions, including, but not limited to, obtaining, entering, validating, or processing patient information or data. [20 CSR 2220-2.725(1)(A)]*

Remote data entry is not limited to just prescription processing, but also includes any entry of data by a pharmacy technician/intern pharmacist into the pharmacy's system from outside of the pharmacy that will be used by the pharmacy to dispense a prescription or provide pharmacy services (see exception below for activities incidental to authorized non-dispensing functions under 20 CSR 2220-6.055).

Effective May 30, 2022, remote data entry sites can be located in any U.S. state or territory, however, the site must be operated and supervised by a Missouri licensed pharmacy that is located in Missouri. [20 CSR 2220-2.725(1)]

The supervising pharmacy must maintain a current list of all remote data entry sites and current policies and procedures governing all aspects of remote data entry site operations, including:

- Authorized technician and intern pharmacist activities
- Remote data entry site security procedures/requirements
- Requirements/procedures for reporting security breaches
- Quality assurance review procedures, and
- Required staff education/training.

The required policies/procedures must be reviewed annually by the supervising pharmacy's pharmacist-in-charge (PIC); The date of the PIC's annual review must be documented in the pharmacy's records. [20 CSR 2220-2.725(4)]

Except as otherwise provided by state and federal requirements, the remote data entry site and the supervising pharmacy must share a common database or prescription record-keeping system that allows real-time, online access to relevant patient profile information by both the supervising pharmacy and the remote site. [20 CSR 2220-2.725(3)(B)]

The identity of a pharmacy technician or intern pharmacist remotely entering, validating, or modifying data at a remote data entry site must be electronically documented/recorded in the supervising pharmacy's records and maintained for five (5) years (e.g., initials/computer code). [20 CSR 2220-2.725(3)(B)]. The identity of the verifying pharmacist must also be documented in the pharmacy's electronic data processing system (e.g., initials, unique code) [20 CSR 2220 2.080(2)(L)]

Supervision: A pharmacist must be available to respond to technician/intern pharmacist questions at all times a remote data entry site is in operation. Additionally, a sufficient mechanism must be in place to allow the supervising pharmacist and pharmacy technician/intern pharmacist to communicate in real-time when needed. Data entry may not be performed at a remote data entry site if the required real-time communication mechanism is not operating or available. Video technology is recommended, but not required. [20 CSR 2220-2.725(3)]

The supervising pharmacist, PIC, and permit holder are responsible for ensuring full compliance with state and federal law. A Missouri-licensed pharmacist must verify the accuracy of prescription/medication order data entered by a pharmacy technician/intern pharmacist at a remote data entry site before dispensing. [20 CSR 2220-2.080(1)]

Staff Training Requirements: Pharmacy technicians/intern pharmacists assisting at a remote data entry site must be competent in the duties performed. Pharmacy technicians/intern pharmacists must have completed employer approved training in the activities performed and must have a documented initial and annual competency assessment. [20 CSR 2220-2.725(3)(C)] The form and content of the required training/competency assessment is in the pharmacy's discretion. Documentation of training and competency assessment(s) must be maintained in the pharmacy's records for at least two (2) years.

Security: Adequate security and supervision must be maintained at the remote data entry site at all times to prevent unauthorized access to confidential records and the remote data entry site/equipment. Any security breach of confidential records or remote data entry equipment must be documented and reported to the board in writing within seven (7) days of the breach. [20 CSR 2220-2.725(3)(A)] Notifications should be e-mailed to the Board office at pharmacy@pr.mo.gov.

To ensure patient confidentiality, paper patient or prescription/medication order records may not be generated, located, printed, or maintained at a remote data entry site. This includes faxed prescriptions that will be printed at the remote site (fax to electronic prescriptions are acceptable if the electronic prescription will not be printed at the remote data entry site). A remote data entry site cannot accept a written

prescription from the patient or the prescriber.

- *20 CSR 2220-2.725 only applies to remote data entry activities performed by a pharmacy technician/intern pharmacist. A Missouri licensed pharmacist may continue to perform non-dispensing activities like data entry, at a non-pharmacy location, as authorized by 20 CSR 2220-6.055*
- *20 CSR 2220-6.055 (Non-Dispensing Activities) allows pharmacy technicians/ intern pharmacists to assist a pharmacist with non-dispensing functions outside of a pharmacy. 20 CSR 2220- 2.725 and the remote data entry requirements would not apply to periodic data entry by a pharmacy technician or intern pharmacist at an off-site location that is incidental to activities being performed under 20 CSR 2220-6.055 (Non-Dispensing Activities). However, 20 CSR 2220-2.725 and the remote data entry requirements would apply to pharmacy technicians/intern pharmacists regularly performing remote data entry outside of a pharmacy, unless a pharmacist is physically present and supervising when the remote data entry activities occurred.*

H.4 FINAL PRODUCT VERIFICATION

A pharmacist must personally inspect and verify the accuracy of all prescriptions/ medication orders before dispensing or personally verify the final product using an electronic final product verification system that complies with 20 CSR 2220-2.011 (see H.5. below). The final check must include inspection/verification of the accuracy of the contents and the affixed label. [20 CSR 2220-2.010(1)(B)].

See the following rules for exceptions to the final verification requirements:

- 20 CSR 2220-2.012 (Technology Assisted Verification of Non-Controlled Medication by an Intern Pharmacist/Pharmacy Technician/Section H.6)**
- 20 CSR 2220-2.600 (Class-F: Renal Dialysis Pharmacy)**
- 20 CSR 2220-2.675 (Class-L: Veterinary Pharmacy/Section D.13)**
- 20 CSR 2220-2.685 (Class Q: Charitable Pharmacy/Section D.15)
- 20 CSR 2220-2.680 (Class R: Remote Dispensing Site Pharmacy/Section D.16)**
- 20 CSR 2220-2.900 (Automated Dispensing Systems)**
- 20 CSR 2220-2.950 (Automated Filling Systems/Section H.28)**

** Additional compliance requirements apply.

Licensees should take proactive steps to prevent and detect medication errors. The Board encourages licensees to report dispensing errors to the USP-ISMP Medication Errors Reporting Program. This confidential program gathers and analyzes data to help prevent future errors. Reports may be submitted online at www.ismp.org.

Radiopharmaceuticals: The Board recognizes that visual verification may not be safe or possible for some radiopharmaceuticals. Pharmacists should comply with 20 CSR 2220-2.500 (Nuclear Pharmacy) and take all appropriate and necessary steps to ensure accuracy of the final product and affixed unit dose label.

- *The Board has received complaints from patients regarding medications that look physically different being commingled in the same patient vial/container (e.g., medication from different manufacturers). This practice may confuse patients and could impact medication adherence if patients are unsure of which medication to take. The Board recommends that licensees either avoid commingling medications that look different in the same vial/container or that licensees*

proactively counsel patients when medication with a different appearance is commingled.

H.5 Electronic Final Product Verification (Pharmacists)

A Missouri licensed pharmacist may use an electronic verification system (EVS) to verify the final prescription/medication order and affixed label, in lieu of personally verifying the final prescription contents and label as required by 20 CSR 2220-2.010(1)(B). The type of EVS used is in the pharmacy's discretion, however, the EVS must allow the pharmacist to see an "exact, clear, and unobstructed visual image(s)" of the filled prescription/medication order contents and the label affixed to the container. [20 CSR 2220-2.011(1)(A)]. This means the medication must be in the actual prescription vial, container, or packaging that will be given to the patient.

- Staff cannot capture an image of just a stock bottle or a print out of the label that will be attached at a later point. While stock bottle images may provide another safety check, the pharmacist must be able to see the actual prescription contents and the label affixed to the dispensing container.
- If multiple units are being dispensed, the pharmacist must be able to see and verify an image of EACH unit and EACH individual affixed label. [20 CSR 2220-2.011(1)(A)] *Note: Verifying multiple images at the same time increases the risk of a dispensing error. Licensees should exercise caution here and make sure pharmacy staff are appropriately trained.*

Pharmacies may choose to capture a real-time, "live" image when using an EVS or use capture and store/forward technology, provided the prescription/image is verified by a pharmacist before dispensing. A bar code scanning system does not comply with the rule unless the system also allows a pharmacist to see the required visual images.

The identity of the pharmacist responsible for verifying the final product using an EVS must be documented in the pharmacy's records as required by 20 CSR 2220-2.080(2)(M). No further manipulation of the prescription/medication order may occur after the pharmacist's electronic verification is complete other than applying the required container lid or seal. For purposes of 20 CSR 2220-2.011, manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage (e.g., bagging the prescription).

Except as otherwise provided by law, compounded preparations cannot be verified via an EVS. Compounded preparations must be personally verified by a pharmacist. *Note: Technology can be used to assist with verifying compounded preparations, provided the final preparation is inspected and verified by a pharmacist as required by 20 CSR 2220-2.010.* [20 CSR 2220-2.011(1)(A)]

- *Pharmacies may verify the final EVS images and labels from home or outside of a pharmacy, provided proper security and procedures are in place to ensure patient confidentiality and data maintenance/integrity.*
- *Pharmacists can also verify the final product via an EVS while located at another pharmacy, if the verifying pharmacist holds a Missouri pharmacist license and both pharmacies have a Class J Shared Services permit and comply with the Class J Shared services rule (20 CSR 2220-2.650). For pharmacists outside of Missouri, the pharmacist must either be licensed in Missouri or the pharmacy must be licensed as a Missouri non-resident pharmacy.*

Staff Training: Pharmacy technicians and intern pharmacists assisting the pharmacist with electronic

verification must be trained and competent to perform the duties assigned and must have a documented initial and annual competency assessment using the pharmacy's approved EVS. [20 CSR 2220-2.011(1)(B)] Staff should know what to do when a malfunction is suspected or occurs (see below for system overrides). While pharmacy staff can assist with EVS activities, the final product verification must be completed by a pharmacist and cannot be delegated to an intern pharmacist or pharmacy technician.

A pharmacist must review and authorize overrides performed by a pharmacy technician or intern pharmacist of any technology generated errors, warnings, alerts, or exceptions related to system functioning or medication verification/accuracy before dispensing. [20 CSR 2220-2.011(2)] Documentation of the pharmacist's review and authorization must be maintained in the pharmacy's records for two (2) years. Pharmacy technicians and intern pharmacists cannot independently override notifications related to system functioning or medication verification/accuracy under any circumstances.

Significantly, 20 CSR 2220-2.011 does not exempt a pharmacist from Missouri's supervision requirements. 20 CSR 2220-2.010 still provides a pharmacist must be physically present at the pharmacy and supervising whenever a prescription is filled, prepared, compounded, or dispensed, except as otherwise authorized by law for Class L Veterinary pharmacies, Class F Renal Dialysis pharmacies, Class Q Charitable pharmacies, and Class R Remote Dispensing Sites.

While an EVS system may provide an additional verification tool, pharmacists should not abandon their clinical skills and should use their professional judgment to ensure accurate dispensing regardless of verification method.

System Validation: EVS systems must be implemented and validated by a pharmacist prior to initial use to confirm the system is functioning properly. Additionally, the system must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures. [20 CSR 2220-2.011(2)] Proof of validation/revalidation must be maintained and documented in the pharmacy's records for two (2) years. At a minimum, validation/revalidation documentation must include the identity of the pharmacist performing the required validation/revalidation and validation/testing date(s) and results. [20 CSR 2220-2.011(2)(B)].

Electronic verification systems must be maintained in good working order. Use of the electronic verification system must be terminated if the system is not properly functioning and the root cause of the malfunction identified and corrected before further use. [20 CSR 2220-2.011(2)] Board inspectors will ask for proof of compliance on inspection/investigation. Staff should be appropriately trained on pharmacy policies/procedures and know what to do in the event of a suspected or actual system malfunction.

Quality Assurance: Pharmacies using an EVS must maintain an ongoing and documented quality assurance system that monitors EVS performance and the electronic assisted verification process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors and system malfunctions. [20 CSR 2220-2.011(3)] Proof of compliance will be requested on inspection.

Policies and Procedures: Pharmacies using an EVS must maintain current, written policies and procedures governing all aspects of electronic-assisted verification activities, including, but not limited to:

1. Staff training and competency assessments;
2. Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;
3. Testing, validation, and revalidation of electronic verification technology to ensure proper

functioning; and
4. System maintenance, including, any routine or preventative maintenance. [20 CSR 2220-2.011(4)]

H.6 Technology Assisted Verification (Interns and Technicians)

Effective August 30, 2022, a Missouri licensed pharmacist may allow an "authorized pharmacy technician" or "authorized intern pharmacist" to verify a final prescription/ medication order for a non-controlled substance using a technology assisted verification system (TAVS), in lieu of final product verification by a pharmacist. [20 CSR 2220-2.012.] A TAVS is defined as:

> *An electronic system that utilizes barcode technology or another electronic process/method to electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient.* [20 CSR 2220-2.012(1)(D)]

Intern pharmacists/pharmacy technicians may only use a TAVS to verify non-controlled substances. [20 CSR 2220-2.012(2)(A)] A TAVS cannot be used to verify controlled substances under any circumstances. Additionally:

1. A TAVS can only be used to verify medication that will be dispensed in the original manufacturer's unopened unit of use package, or medication that has been repackaged in compliance with 20 CSR 2220-2.130 and previously verified by a pharmacist;
2. The authorized pharmacy technician or intern pharmacist must be under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance;
3. The authorized pharmacy technician/intern pharmacist must be competent to perform the duties assigned and must have completed a documented initial and annual assessment of competency using the pharmacy's approved TAVS;
4. A pharmacist must verify the accuracy of prescription/medication order data entry prior to dispensing and complete a prospective drug utilization review. The identity of the pharmacist verifying data entry must be recorded in the pharmacy's records as required by 20 CSR 2220-2.080;
5. The TAVS must be used to verify the proper prescription label has been affixed to the correct manufacturer unit of use package or repacked container for the correct patient;
6. No manual manipulation of the prescription/medication order may occur after the TAV occurs. For purposes of 20 CSR 2220-2.012, manual intervention does not include preparing a finished prescription/medication order for mailing, delivery, or storage (e.g., bagging); and
7. The identity of both the authorized pharmacy technician or intern pharmacist performing the TAV and the supervising pharmacist must be documented in the pharmacy's records. [20 CSR 2220-2.012(2)]

Non-controlled prescriptions/medication orders that have been verified by an authorized intern pharmacist or authorized pharmacy technician using a TAVS in compliance with 20 CSR 2220-2.012 do not have to be verified again by a pharmacist. However, a pharmacist has to verify the accuracy of prescription/medication order data entry before dispensing and complete a prospective drug utilization review. [20 CSR 2220-2.012(2)]

An **authorized intern pharmacist** is defined as "*an individual who holds a current and active Missouri intern*

pharmacist license and has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system". An "**authorized pharmacy technician**" is defined as a currently registered Missouri pharmacy technician who:

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;*
2. Has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; and
3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year. [20 CSR 2220-2.012(1)(B)]

*** Note: As of January 2023, the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA/ExCPT) are accredited by NCCA.*

Proof of compliance with the training, practice and qualification requirements must be maintained in the pharmacy's records for two (2) years and made available on inspection/request by the Board.

- *Use of a TAVS is only authorized if allowed by a Missouri licensed pharmacist, even if the intern pharmacist/pharmacy technician meets the requirements. Technicians/intern pharmacists still have to be under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance whenever medication is being prepared/dispensed or verified using a TAVS.*

SUPERVISION LIMITS: A pharmacist may not supervise more than two (2) pharmacy technicians or intern pharmacists performing TAV simultaneously. [20 CSR 2220-2.012(2)(C)] The pharmacist-in-charge may petition the board to increase the number of supervised technicians/intern pharmacists for good cause. Petition requests should be submitted in writing to the Board office or e-mailed to: pharmacy@pr.mo.gov.

SYTEM VALIDATION/QUALITY TESTING: Technology assisted verification systems must be maintained in good working order, and must verify prescriptions/medication orders and the affixed labels with one hundred percent (100%) accuracy. Use of the TAVS must be terminated and the root cause identified and corrected if a verification error is detected. [20 CSR 2220-2.012(3)]

The TAVS must be implemented and validated by a pharmacist prior to initial use to confirm the technology's accuracy and correctness. At a minimum, the TAVS must complete one thousand (1,000) consecutive product verifications during the initial validation process with a one hundred percent (100%) accuracy rate. While a vendor or pharmacy staff may assist with initial validation, a pharmacist must audit one hundred percent (100%) of the product verifications completed during the initial validation process before dispensing and confirm accuracy.

The TAVS must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures. The revalidation process must include a sampling of prescriptions/medication order verifications by the TAVS using a sample size that is sufficient to confirm the technology is properly and accurately functioning. Pharmacies should establish policies/procedures for selecting a valid sample size. Similar to initial validation, a pharmacist must audit and verify one hundred percent (100%) accuracy of the sampled verifications prior to further use of the TAVS.

To ensure ongoing functioning, a pharmacist must also conduct daily random quality testing on at least two

percent (2%) of prescriptions/medication orders verified via the TAVS on the last day the system was operated. Pharmacy staff must immediately stop using the TAVS and the root cause identified and corrected if quality testing results show less than 100% accuracy.

The required validation/revalidation audits and daily random quality testing must be conducted by a pharmacist and cannot be delegated to an intern pharmacist, pharmacy technician, or outside vendor. Proof of compliance with validation, revalidation, and testing requirements must be documented and maintained in the pharmacy's records for two (2) years. At a minimum, documentation must include the name, initials, or identification code(s) of the pharmacist performing the required validation/testing and validation/testing date(s) and results.

Staff should be appropriately trained on TAVS policies/procedures and know what to do in the event of a suspected or actual system malfunction. Only a pharmacist can initiate the operation of a TAVS or override technology generated errors, warnings, alerts, or exceptions related to TAVS functioning or medication verification/accuracy before dispensing. [20 CSR 2220-2.012(3)] Documentation of the pharmacist's review and authorization must be maintained in the pharmacy's records for two (2) years. Pharmacy technicians and intern pharmacists cannot independently override notifications related to system functioning or medication verification/accuracy under any circumstances.

Quality Assurance: Pharmacies using an EVS must maintain an ongoing and documented quality assurance system that monitors the performance of the EVS and the electronic assisted verification process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors, system malfunctions, and other compliance concerns. [20 CSR 2220-2.012(5)] Proof of compliance will be requested on inspection.

Pharmacies must notify the Board electronically or in writing of any dispensing error involving a TAVS that reaches the patient within ten (10) days of discovery. The notification must include the date of the incident, patient name, the technician or intern pharmacist who performed the TAV, a description of the error, the applicable prescription/medication order number or unique identifier, and the supervising pharmacist of record. [20 CSR 2220-2.012(5)]

Policies and Procedures: Pharmacies using a TAVS must maintain current, written policies and procedures governing all aspects of electronic-assisted verification activities, including, but not limited to:

1. Staff training and competency assessments;
2. Operation of the required quality assurance system, including reporting, investigating, and addressing errors, system malfunctions, and other quality assurance issues;
3. Testing, validation, and revalidation of the TAVS to ensure proper functioning; and
4. System maintenance, including any routine or preventative maintenance. [20 CSR 2220-2.012(6)]

H.7 LABELING

A written/printed label must be affixed to each prescription container dispensed to a consumer that indicates:

1. The date the prescription was filled;
2. A prescription number or other unique identifier;
3. The patient's name;
4. The prescriber's directions for use;

5. The prescriber's name;
6. The pharmacy's name and address; *(For Class-J pharmacies, either the name and address of the pharmacy responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label, as designated by the pharmacies by contract)*;
7. The exact name and dosage of the drug dispensed, and;
8. If a generic substitution is made, the drug manufacturer must be identified either on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Board inspectors have observed instances where the generic product is listed on the label with the statement "substituted for" followed by the brand name of the product. This is acceptable if the label is not misleading. However, Missouri law doesn't require that a brand name be on a label when a substitution is made.

For controlled substance prescriptions issued by a Missouri APRN or physician assistant, the label must also include both the names of the prescribing mid-level practitioner and their supervising or collaborating physician [§ 195.100, RSMo]. The supervising or collaborating physician's name is not required on the label for controlled substances prescribed by an assistant physician.

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable. *Note: These labeling requirements do not apply to internal drug "orders" for in-patients of a licensed hospital.*

- *The most common label discrepancy that inspectors observe involves "PRN" in the label directions. Either "as needed" is omitted from the label directions when prescribed as "PRN," or "as needed" is included in the label directions when not prescribed as "PRN". The inclusion or exclusion of "PRN" can be clinically significant, and may result in the patient either taking more medication than needed or not taking medication when medically appropriate. This is especially important with opiates in light of the ongoing opioid crisis. Pharmacists should pay careful attention when verifying prescriptions to make sure the prescribed directions are correct.*

H.8 PATIENT COUNSELING

Except as otherwise required for Class R Remote Dispensing Site Pharmacies, patients must be offered the opportunity to consult with a Missouri-licensed pharmacist each time a prescription is dispensed (new or refill). [OBRA 90; 20 CSR 2220-2.190]. The offer to counsel may be extended by pharmacy staff, however, patient counseling may only be provided by a Missouri-licensed pharmacist or a Missouri-licensed intern pharmacist acting under the pharmacist's immediate supervision. [20 CSR 2220-2.190]. (See D.16 for mandatory patient counseling requirements for Class R pharmacies)

- If the medication is picked up by the patient or caregiver, a verbal offer to counsel must be made.
- If the medication is mailed or delivered to the patient, the patient must be given a written offer to counsel with their medication along with a toll-free telephone number for the dispensing pharmacy (unless a verbal offer to counsel is made in advance or when the prescription is delivered). [20 CSR 2220-2.190(1)]. The written offer must include a statement that the patient may call the pharmacy if the patient has questions. A phone number alone is insufficient. A written offer cannot be used to replace the required verbal offer when medication is picked up at the pharmacy.
- For Class Q Charitable Pharmacies, a verbal offer to counsel must be made. If a pharmacist is not

present at the pharmacy or unavailable, the patient must be given a written offer to counsel with their medication along with a telephone number for a pharmacist. [20 CSR 2220-2.190(1)].

- For Class R Remote Dispensing Site Pharmacies patient counseling is mandatory unless refused by the patient. An offer to counsel is not sufficient.

Patient counseling is one of the most important patient care services a pharmacist provides. Patients should be clearly asked if they have any questions for the pharmacist or would like to speak with a pharmacist about their medication. Broad questions such as, "Any questions?" or "Do you need anything else?" may be confusing and lead to patients unintentionally declining counseling.

If counseling is requested, pharmacists should use their clinical skill to determine how to effectively communicate with the patient. Counseling should include matters that will, in the professional judgment of the pharmacist, enhance or optimize therapy and allow the patient to safely and appropriately use the prescribed medication or device/equipment. [20 CSR 2220-2.190(1)] Additionally, licensees must comply with all applicable state and federal laws when counseling, including, state and federal laws governing patient privacy/confidentiality, medication guides, and federal risk evaluation and mitigation strategy (REMS) requirements. The Board also recommends counseling patients on the following (as applicable):

1. The medication name and description;
2. The dosage, dosage form, route of administration and duration of therapy;
3. Any special directions or instructions for patient use, preparation or administration;
4. Significant side effects, adverse effects or interactions, and therapeutic contraindications;
5. Techniques for self-monitoring;
6. Proper storage;
7. Appropriate disposal methods;
8. Refill information;
9. Suggested action in the case of a missed dose or equipment/device malfunction; and
10. Any other matter deemed necessary or appropriate in the pharmacist's professional judgment to allow the patient to safely and appropriately use the prescribed medication, device or medical equipment and maximize therapeutic outcomes. (This list is suggested and not mandatory)

Counseling may be provided in-person or via an electronic mechanism that allows the pharmacist and patient/caregiver to communicate in real-time with the patient either verbally or face-to-face.

Patient counseling is not required if:

- The patient is an inpatient of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications, or;
- The patient or caregiver refuses consultation. [20 CSR 2220-2.190(4), (5)].

Intern pharmacists may provide patient counseling while under pharmacist supervision, however, pharmacy technicians cannot provide patient counseling under any circumstances. Board Inspectors have observed multiple instances of technicians intentionally or inadvertently providing patient counseling in violation of the law, including:

- Technicians answering patient questions about a medication's indication
- Pharmacists telling a technician what to say in response to a counseling request
- Technicians recommending over-the-counter (OTC) products to treat a specific ailment
- Technicians explaining medication storage and administration requirements (even when this information is being read from the prescription label or auxiliary labels), and
- Technicians informing patients of side effects they may experience after being vaccinated or taking

prescription/OTC medication.

These activities constitute patient counseling and cannot be performed by a technician under any circumstances. Talk with pharmacy staff to make sure they understand what constitutes patient counseling and what technicians are allowed to do.

> The Board is aware of instances where delivery drivers are delivering medication to the patient and verbally offering patient counseling that is provided by a pharmacist electronically or on the phone. A toll-free number and written offer to counsel is not required in these instances if a verbal offer is given and the patient is able to promptly consult with a pharmacist at the time the prescription is delivered either verbally or electronically (e.g., via video chat/tablet/phone).

H.9 PATIENT PROFILES

Licensees are required to collect and maintain appropriate patient information to facilitate patient counseling. The Board recommends collecting any information that may be needed to effectively provide patient care. Appropriate information may include, but is not limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies, and a list of other drugs prescribed. [20 CSR 2220-2.190(2)]

H.10 PATIENT IDENTIFICATION

Missouri law requires valid photo identification for patients purchasing Schedule 5 methamphetamine precursor products (e.g., pseudoephedrine, ephedrine, phenylpropanolamine) [19 CSR 30-1.074(3)] Missouri does not require photo identification for other prescriptions although pharmacies may choose to implement their own requirements (other federal laws/payer requirements may also apply).

The Board has reviewed multiple cases where errors could have been prevented if the patient was correctly identified. In other cases, impersonators have been able to pick-up valid prescriptions using stolen patient information. To prevent confusion, the Board recommends using multiple identifiers to identify patients (e.g., birth date & address).

Licensees are required to positively identify recipients of medication dispensed via a vacuum tube delivery system. See E.11. While photo ID is recommended, other identifiers may be used.

H.11 GENERIC SUBSTITUTION [§ 338.056]

Pharmacists may use their professional discretion to substitute a less expensive generic or interchangeable biological product when filling a prescription/medication order, unless:

1. The patient requests a brand name or biological product; or
2. The prescriber indicates substitution is prohibited in some manner or writes "brand medically necessary," "dispense as written," "do not substitute", "DAW" or any similar language that indicates substitution is prohibited. [§ 338.056]

For verbal prescriptions, pharmacists must document the prescriber's instructions on substitution. [§ 338.056.4].

If a generic product is substituted, the manufacturer's name or abbreviation must be identified on the

prescription label or in the pharmacy's records. [§ 338.059(9)] A pharmacist may not substitute with a drug (new or refill) that has been rated by the FDA as inequivalent, or a biological that has not been rated by the FDA as interchangeable, without prescriber approval. [20 CSR 2220-3.011(3)]

H.12 INTERCHANGEABLE BIOLOGICAL PRODUCTS [§ 338.055, § 338.056]

Pharmacists may substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber. [See § 338.056, § 338.085]. An "interchangeable biological product" is defined as a biological product that the FDA:

a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. § 262(k)(4); or
b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). [§ 338.085.1]

The FDA's list of interchangeable biologicals may be found at: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm (Purple Book).

Patients must be informed that an interchangeable biological product has been substituted either verbally or in writing. [§ 338.085.2] Additionally, the prescriber must be notified of the substituted product name and manufacturer within five (5) days of dispensing. Prescriber notification is not required if no FDA approved interchangeable biological product exists for the product prescribed or the prescription is a refill and no changes have been made from the prior filling. [§ 338.085.3]. Notifications can be made in writing or electronically (e.g., e-mail, fax). Alternatively, notification can be made via an electronic record system that can be accessed by the prescriber (e.g., an EMR or an e-prescribing or electronic pharmacy/PBM system). Licensees must comply with all other Board rules applicable to generic substitutions, including, all labeling and recordkeeping requirements.

H.13 DRUG UTILIZATION REVIEW

20 CSR 2220-2.195 provides a pharmacist must conduct a prospective drug utilization prior to dispensing a prescription or medication order (new and refill). Pharmacists should use their clinical judgment to assess therapeutic appropriateness on a case-by-case basis. Board suggested review items include:

1. Drug over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Food, nutritional supplement, or over-the-counter medication interactions;
6. Inappropriate drug dosage or treatment duration;
7. Drug-allergy interactions;
8. Clinical abuse/misuse; and
9. Any other factor deemed necessary or appropriate within the pharmacist's professional judgment to assess the adequacy of patient care/medication therapy.

The above items are suggested only. A review of other factors may be clinically appropriate in a given case. Once again, pharmacists should use their clinical judgment here to ensure an adequate DUR is performed.

The Board recognizes that pharmacists may have limited—or no—access to a physician's medical records or

the patient's health records. 20 CSR 2220-2.195 only requires that a pharmacist review patient records that are "available" to the pharmacist when assessing therapeutic appropriateness (e.g., the patient's prescription records, etc.)

The required prospective DUR must be performed by a Missouri-licensed pharmacist or by a Missouri-licensed intern pharmacist under a licensed pharmacist's supervision. If the DUR is delegated to an intern, the supervising pharmacist remains responsible for ensuring an appropriate DUR is performed in compliance with applicable standards of care. If multiple pharmacists are involved in dispensing or approving medication (e.g., PV1 / PV2), the pharmacy's policies and procedures should clearly identify which pharmacist is responsible for conducting the required DUR. The Board strongly recommends documenting the identity of the pharmacist who completed the DUR. Proof of compliance may be requested on inspection.

The prospective DUR requirement applies to all prescriptions and medication orders (new and refill). The rule also applies to pharmacists who are approving medication for dispensing, as well as pharmacists who are approving medication before it is provided to the patient but are not involved in the actual dispensing process (e.g., consultants).

Electronic DUR Tools: A variety of electronic DUR tools are available or incorporated into pharmacy software systems. While electronic DUR tools can be helpful, pharmacists cannot abandon their clinical skills. Instead, pharmacists should independently assess therapeutic appropriateness for the specific patient based on available records. Electronic DUR programs/tools should not replace the pharmacist's clinical skills or professional judgment.

The Board recommends documenting the grounds for overriding electronic DUR alerts generated by the pharmacy's system and the pharmacist responsible for the override. Although not required, this documentation is a good best practice that can be useful for more than just billing. For example, the documentation can help track/support clinical activities and may also be beneficial in the event of a staffing change or a patient complaint. The Board has reviewed a number of complaints/investigations where the pharmacy was unable to provide supporting documentation for why an override was appropriate. In some instances, the pharmacist had lengthy discussions with the prescriber but failed to note/record any of their activities. If you do it, document it!

- The Board has reviewed instances where pharmacy technicians were allowed to independently override drug utilization (DUR) alerts without consulting with a pharmacist. DUR requires a pharmacist's professional judgment; DUR alerts should be reviewed by a pharmacist and only cleared/overridden with a pharmacist's approval.
- The Missouri Department of Health and Senior Services' (DHSS) has regulatory jurisdiction over pharmacy services provided within the "licensed premises" of a Missouri hospital. Pharmacy services under DHSS' authority would need to comply with DHSS requirements; The Board's DUR rule would not apply. However, Class-B hospital pharmacies are under the Board's jurisdiction and must comply with 20 CSR 2220-2.195.
- The Board recognizes that DUR procedures may be different/limited for nuclear pharmacies. Pharmacists dispensing radiopharmaceuticals should make a good faith effort to conduct the required DUR based on known/available information, which the Board recognizes may be limited in some instances.

H.14 FLAVORING

Licensees may flavor a legend product unless the prescriber indicates otherwise. OTC products may only be flavored by prescription. Licensees should indicate that the product was flavored on the patient's container and the added flavoring must be documented in the pharmacy's prescription record (e.g., in a flavoring book or in the prescription record). As defined by the Board's rules, flavoring does not constitute compounding. Licensees may not flavor a prescription dispensed by another pharmacy.

> The Board is aware that USP is reviewing whether flavoring constitutes compounding. The Board has not adopted USP's proposed revision at this time but may reconsider this approach in the future.

H.15 SYRINGES & OVER-THE-COUNTER MEDICATION

OTC: Pharmacies dispensing a prescription for an over-the-counter medication must comply with all prescription requirements if the medication is dispensed and treated as a prescription.

Syringes: Missouri does not require a prescription in order to sell OTC insulin syringes to patients. However, other types of syringes are labeled as legend devices. Any syringe bearing the federal legend, *"Rx Only" or "Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician"* would require an order from a prescriber. Licensees should note the federal legend may be on the outer packaging label instead of the individual syringe label. Pharmacists should look at both labels to determine if a syringe is a legend or OTC product.

H.16 CONSOLIDATION OF REFILLS [§ 338.202]

Section 338.202, RSMo, allows a pharmacist to consolidate refills of non-controlled maintenance medication up to a ninety-day (90) supply. "Maintenance medication" is defined as a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

To consolidate, the maintenance medication must have been previously prescribed to the patient for at least a three-month period. Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a 90-day supply may be dispensed at one time. The 90-day supply limit does not apply:

1. If the prescription is dispensed to a member of the U.S. Armed Forces serving outside of the United States, or;
2. The prescription was issued by a practitioner located in another state, provided the prescription must be issued "according to and in compliance" with federal law and the applicable state's law.

Consolidation is not allowed if the prescriber indicates that dispensing the initial amount followed by periodic refills is medically necessary. Section 338.202 applies to non-controlled prescriptions only. Controlled substances cannot be consolidated.

The Board has been asked if the required 3-month patient use period has to be consecutive or if prior fills/refills must have been dispensed by the same pharmacy. Missouri law is silent on both of these questions. Absent further statutory clarification, licensees may consolidate refills for patients prescribed a maintenance medication for any 3-month period even if prior fills/refills were dispensed by another

pharmacy.

Pharmacists should exercise their professional judgment when consolidating refills as consolidation may not be appropriate for all patients. The Board recommends informing patients if any additional costs/insurance requirements apply prior to dispensing.

H.17 EMERGENCY DISPENSING [§ 338.200]

Section § 338.200, RSMo, allows a Missouri pharmacist to dispense an emergency supply of non-controlled medication if the pharmacist is unable to obtain refill authorization from the prescriber. Pharmacists may dispense an emergency supply if:

- In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable consequences;
- The pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication;
- The emergency dispensing is documented in the patient's prescription record;
- The drug is not a controlled substance; and
- The pharmacist informs the patient or the patient's agent at the time of dispensing that prescriber authorization is required for future refills. Notification can be made verbally, electronically or in writing.

The emergency supply must be limited to the amount needed for the emergency period as determined by the pharmacist within his or her professional judgment. However, the total amount dispensed cannot exceed a seven-day supply. If the prescriber is deceased, incapacitated or unable to provide medical services, up to a thirty-day supply may be dispensed.

The prescriber or the prescriber's agent must be promptly notified after an emergency supply is dispensed. An emergency supply may not be dispensed if the medication is a controlled substance or the pharmacist has knowledge that the prescriber has prohibited or restricted emergency dispensing for the patient.

> *The Board recognizes certain medications are dispensed in manufacturer packaging that exceeds a seven day supply. However, § 338.200.2 provides the amount dispensed shall "not exceed a seven day supply" if the prescriber is not deceased or otherwise incapacitated. Pharmacists should consult with legal counsel and use their professional judgment as needed for the emergency period in such circumstances.*

H.18 PRESCRIPTION DELIVERY SITES

Pursuant to 20 CSR 2220-2.013, prescriptions filled by a Missouri pharmacy "may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy." However, filled prescriptions may be delivered to the following locations at the request of the patient or the patient's authorized designee:

- The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
- A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;
- A hospital, office, clinic or other medical institution that provides health care services;
- A residence designated by the patient or the patient's authorized designee, or;
- The patient's office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified in the rule only if the

prescription is delivered directly to the patient or the patient's authorized designee. Additionally, prescriptions for veterinary use may be delivered to a residence, business, or clinic if requested by the customer. Except as otherwise allowed for Class Q Charitable pharmacies, a Class-J pharmacy license is required if filled prescriptions are delivered to another pharmacy for patient pick-up (see D.15 for charitable pharmacies).

Patient/designee authorization may be received verbally, electronically or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy's records. Rule 20 CSR 2220-2.013 applies to all Missouri licensed pharmacies delivering filled prescriptions regardless of delivery method (e.g., mail order, employee delivery, or common carrier).

Pharmacies delivering medication as allowed by the rule must develop written policies and procedures "to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer" or USP. Policies and procedures should be maintained at the pharmacy or accessible for review during an inspection or if requested by a Board designee. A prescription delivery policy/procedure is not required if the pharmacy doesn't deliver filled prescriptions.

> *The Board understands licensees cannot control or predict the activities of third party carriers. The Board also recognizes extenuating circumstances may occur that are beyond a licensee's control. Licensees should establish policies and procedures to ensure delivery within appropriate temperature requirements given normal and customary delivery times. It is also recommended that licensees establish a mechanism for patients to report delivery concerns.*

Return to Stock: Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy location that are not picked up by the patient cannot be returned to stock.

Controlled Substances: Licensees must comply with all applicable controlled substance laws and regulations when delivering medication, including, but not limited to, all applicable security requirements.

Section 195.070, RSMo, was amended in 2020 to allow filled controlled substance prescriptions to be delivered to a healthcare practitioner for administration to the patient prescribed the medication. However, BNDD has advised the new law cannot be implemented until BNDD finalizes the required administrative rules. Licensees should monitor BNDD's website for additional updates and contact BNDD for questions/compliance information.

- *Can pharmacies deliver to drop sites? No. Prescriptions may only be delivered to a site not specified in the rule if the prescription is delivered directly to the patient or the patient's authorized designee.*
- *The Board's rules do not prohibit dispensing to patients outside of the United States, however, licensees should consult with the FDA and the applicable country/territory to ensure compliance with federal and international laws. Licensees should also consult with BNDD and the DEA if controlled substances are involved.*

H.19 EARLY FILLS/REFILLS

Board inspectors have observed medications being dispensed too soon to the same patient. In some instances, "early fills/refills" may result from filling prescriptions from different prescribers or refilling a prescription on a cycle that does not correlate with previously dispensed amounts. Under state and federal law, pharmacists have a professional obligation to ensure drugs are dispensed for bona fide purposes and are not being abused or diverted due to excessive purchases. Licensees should investigate dispensing patterns that indicate excessive consumption or non-compliance with prescribed directions.

H.20 OFFICE STOCK DISPENSING

To be valid for dispensing, prescriptions must be written by an authorized prescriber for a specific patient. [§ 338.095]. Pharmacies/pharmacists are not allowed to dispense drug products for office stock by prescription (see I.2 for exemptions for veterinary products for animal use).

Pharmacies may, however, transfer medication to an authorized entity by invoice (non-controlled and schedule III-V drugs), or via a DEA 222 form or CSOS (Schedule II drugs). [*See F.13 for additional information on drug transfers*]. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross sales. Total gross sales are calculated based on the pharmacy's total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy's total drug purchases. [§ 338.330(2); 20 CSR 2220-5.020(1)(B)]. *See D.10 for Class B pharmacy exemptions.*

Pharmacies may need to register with the FDA as a repackager if the pharmacy repackages drugs for distribution to other pharmacies or practitioners (see D.10 for repackaging guidance for hospitals/Class-B pharmacies). Additionally, federal law may require that a pharmacy register with the DEA as a controlled substances distributor if the total dosage units of controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year. *See I.2 for compounding for office use/distributing non-patient specific compounded veterinary preparations.*

H.21 TABLET SPLITTING

The Board is aware of licensees using or recommending tablet splitting to lower patient costs or due to insurance/supply issues. The Board is concerned that these practices may not be in the patient's best interest. As licensed professionals, pharmacists must provide medications in their proper form. Only drug products that are scored should be used in tablet splitting. This includes splitting tablets into half or quarter tablets. Drugs that are not scored will likely not split in a manner that will provide a uniform dose. Coated tablets may also present problems because any effect the coating provides may be compromised once the drug is split.

Before tablet splitting, pharmacists should verify that:

1. The literature, or other recognized compendia for the drug, recognizes or indicates that splitting of the specific brand of tablet can be accomplished safely and effectively;
2. The prescriber has approved any change in the prescription strength, and;
3. The patient has received detailed patient counseling to ensure the patient understands the changes made. If the patient is responsible for splitting the tablet, counseling should be provided on splitting techniques and the use of any related items (e.g., tablet splitters).

H.22 PREPACKAGING [20 CSR 2220-2.130]

To assist in dispensing, medication may be removed from the original manufacturer's container and stored in a dispensing container/system until dispensed to a patient (e.g., an automatic dispensing system). Only products that will be directly provided to the patient may be prepackaged.

Proper sanitation procedures must be utilized when prepackaging drugs. Staff must wear disposable gloves when physically touching individual dosage units. [20 CSR 2220-2.010(1)(I)] Additionally, containers and equipment must be properly cleaned and maintained to prevent contamination. Reusable containers should be kept clean of tablet dust and other contaminants.

At a minimum, containers used for prepackaging must meet USP Class B container standards. Light sensitive containers must be used, if applicable. A label must be affixed to the prepacked drug container indicating the drug's name and strength, the manufacturer/distributor, lot number, and the required expiration date. The maximum allowed expiration date is twelve (12) months or the manufacturer's expiration date, whichever is less. In lieu of the required label, licensees that store drugs in an automated counting device may record the required lot number/expiration date in the pharmacy's records, however, the information must be fully traceable and readily retrievable during an inspection.

H.23 PATIENT MED PAKS [20 CSR 2220-2.145]

In lieu of dispensing multiple containers, licensees may dispense medication in a single customized patient medication package ("patient med pak"). Patient med paks must comply with rule 20 CSR 2220-2.145. An authorized "patient med pak" is defined as a package prepared for a specific patient that consists of one or more containers which contain two or more prescribed solid oral dosage forms. Med paks may contain controlled substances, provided the med pak complies with all applicable state and federal controlled substance laws.

Prior to dispensing a med pak, pharmacists must consider:

- Any applicable compendia requirements or guidelines;
- The physical and chemical compatibility of the dosage forms placed in each container; and
- Any therapeutic incompatibilities if the medications are administered simultaneously. *The Board encourages licensees to report any observed or reported incompatibilities to USP.*

** A valid prescription/medical order is required for any OTC product placed in a med pak.*

Containers: Med Pak containers must be non-reclosable or designed to show if the container has been opened. Containers must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container, unless more stringent requirements exist for a drug contained in the med pak. USP has warned about potential physical and/or chemical incompatibilities when certain drugs are packaged together. Pharmacists must ensure that no interactions will occur when preparing multi-med packages.

Labeling: Med paks must be designed or each container labeled to indicate the day and time, or period of time, that the contents in each container should be taken. Med paks must also be labeled with:

1. The patient's name;
2. A serial number for the patient med pak and a separate serial number for each prescription order for each drug contained in the med pak;
3. The name, strength, physical description or identification and total quantity of each drug product;
4. Directions for use and any cautionary statements contained in the prescription order for each drug;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The prescriber's name for each drug product;
7. The preparation date and beyond-use date assigned. The beyond-use date may be no later than ninety (90) days from the date of preparation. *Note: The allowed beyond-use date was extended from sixty (60) days;*
8. The name, address, and telephone number of the dispenser; and
9. Any other information, statements, or warnings required for any included drug.
10. If intact containers can be removed or separated from the patient med pak, each individual container must contain a label that identifies all medication in the container. While not required, the lot, manufacturer, and expiration dates are strongly encouraged for recall and patient safety

reasons.

Package Inserts: Package inserts/medication guides must be provided if required for any drug in the med pak. In lieu of an individual insert, required information may be incorporated into a single, overall insert for the entire med pak.

Records: In addition to the prescription, the following documentation must be maintained for each dispensed med pak:

1. The patient's name and address;
2. The prescription serial number for each drug contained in the med pak;
3. The name of the manufacturer/labeler and lot number for each drug;
4. The preparation date and assigned beyond-use date;
5. Any special labeling instructions;
6. The name or initials of the preparing pharmacist; and
7. Information identifying or describing the design, characteristics, or specifications of the med pak. The med pak must be described in a manner that would allow an identical med pak to be made. [20 CSR 2220-2.145(F)4.]

Returns: Generally, med paks that have been delivered to an institution or to a patient cannot be returned to the pharmacy. However, 20 CSR 2220-2.145(4)(H) provides a pharmacist may modify/repackage a med pak that has been delivered to an institution or patient if:

1. The med pak is returned to the pharmacy that originally dispensed the med pak;
2. The med pak is modified/repackaged per prescription order for the same patient that it was originally dispensed to;
3. The med pak is assigned a new serial number;
4. The med pak is labeled in compliance with 20 CSR 2220-2.145, however, the med pak must retain the original beyond use date assigned to the med pak before modification/repackaging;
5. Medications removed from the med pak are destroyed in compliance with state and federal law. Removed meds cannot be returned to stock or redispensed to either the same or a different patient, and;
6. The pharmacy maintains all records required by 20 CSR 2220-2.145 (see above).

Except as otherwise allowed by 20 CSR 2220-2.145 for modification/repackaging purposes, medication that has been commingled with other drugs in a med pak may not be returned to stock, dispensed, or distributed except for destruction.

Compliance with 20 CSR 2220-2.145 is required even if the container is supplied by the patient (e.g., weekly med tray).

H.24 CHILD RESISTANT CONTAINERS

All dispensed prescriptions must be packaged in a child resistant container unless:

- The physician specifically requests that a non-child resistant container be dispensed. Pharmacists cannot honor blanket requests from a prescriber to never use safety caps for the prescriber's patients, or;
- The patient specifically requests a non-child resistant container. Patients may issue a blanket request for all prescriptions. However, a request on a single prescription cannot be used as a blanket waiver for subsequent prescriptions. The Board recommends documenting patient requests in writing.

The Board has signed an agreement with the Consumer Product Safety Commission ("CPSC") to assist in enforcing child resistant container laws. The Board is required to report significant violations of the child resistant container laws to the CPSC. Under federal law, violations may result in criminal or civil liability. The pharmacy related provisions of the Poison Prevention Packaging Act can be found at 16 CFR 1700.14

H.25 RETURN TO STOCK

A prescription may be returned to stock if:

1. The prescription was not received by or delivered to the patient; and
2. The prescription was maintained in the pharmacy's possession in accordance with the manufacturer's labeled storage requirements at all times. [20 CSR 2220-3.040]

All drugs returned to stock that are not in the original manufacturer container must be maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container (see exemptions below for automated filling systems). Notations may be made on the label to distinguish it from active prescriptions being processed.

If returned to stock, the drug's expiration date must become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. The pharmacy is required to delete the dispensing in the pharmacy's records and reverse/credit any third-party payor claims (e.g., insurance).

Drugs returned to stock may not be poured back into the original stock container because the drug has undergone manipulation outside of its original container. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.

Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy prescription delivery site authorized by 20 CSR 2220-2.013 that are not picked up by the patient cannot be returned to stock. See H.18

Automated Filling Systems: Return to stock medication may be returned to an automated filling system, unit, cell or cartridge containing the same medication if:

1. The prescription/medication order is returned to the automated filling system that originally dispensed it;
2. A pharmacist verifies the return to stock drug is properly stocked and loaded in the system;
3. The expiration date for all drugs in the unit, cell or cartridge where medication is returned must become the shortest expiration of any drug contained in the same unit, cell or cartridge, including, any return to stock medication; and
4. Drugs from different manufacturers may not be commingled in the same unit, cell or cartridge. [20 CSR 2220- 3.040]

Errors/Recalls: As authorized by federal law, the Board has allowed returns to the pharmacy if the wrong medication was dispensed to the patient or in instances of a drug recall. Medication returned by a patient under this authorization cannot be reused or returned to stock under any circumstances. [20 CSR 2220-3.040(3)].

See Q.5 for returns from a LTC facility or from a hospital or hospice facility regulated by the Missouri Department of Health and Senior Services. See H.23 for med-pak returns.

H.26 DRUG TAKE-BACKS

20 CSR 2220-2.095 allows Missouri pharmacies to accept both controlled and non-controlled medication from the public for destruction/disposal.

NON-CONTROLLED MEDICATION

Pharmacies may collect medication for destruction by providing a collection receptacle or via an authorized mail back program. No additional Board notification or registration is required to operate a take-back program, however, participating pharmacies must establish and follow policies/procedures for collecting/destroying medication.

- Collection Receptacles: Collection receptacles must be securely placed and maintained inside the pharmacy's physical building in a manner that prevents theft, diversion or unauthorized removal. Receptacles must be securely locked, substantially constructed containers that are equipped with inner liners for storing medication.
    1. Collection receptacles must be securely fastened to a permanent structure and must be visible to pharmacy staff at all times. Collection receptacles may not be located in or near exit doors. See 20 CSR 2220-2.095 for collection receptacles at long-term care facilities.
    2. Pharmacies only collecting non-controlled substances must post a prominent sign on the outside of the collection receptacle stating that only non-controlled substances may be deposited in the receptacle. Pharmacies collecting controlled substances must comply with all controlled substance laws, including, any controlled substance signage requirements.
    3. Collection receptacles must contain an inner liner that is removable, water-proof, tamper evident and tear-resistant. The inner liner must bear a permanent, unique identification number or other unique identifier that allows the inner liner to be tracked (e.g., a serial number). The inner liner must be constructed of material that prevents the contents of the inner liner from being viewed from the outside.
    4. Installation and removal of inner liners must be supervised by two (2) Board licensees or registrants. Inner liners must be immediately sealed once removed from the collection receptacle. The sealed inner liner cannot be opened, x-rayed, analyzed, or otherwise penetrated by pharmacy staff. Sealed inner liners pending destruction may be stored at the pharmacy in a securely locked, substantially constructed cabinet, or in a secure locked room/area with controlled access, for no more than thirty (30) business days.
    5. Inner liners must be inventoried annually. *See 20 CSR 2220-2.095(8) for additional documentation requirements for inner liners.*
    6. Pharmacy collection receptacles cannot be used to dispose of pharmacy inventory, including returns from long-term care facilities.
    7. Pharmacies must report any theft or diversion from a collection receptacle to the Board in writing within fourteen (14) days. Reports can be mailed to the Board office or e-mailed to compliance@pr.mo.gov
- Mail-Back Programs: For mail-back programs, the public must be provided pre-addressed, postage-paid mail-back packages for returning medication. Mail-back packages must be nondescript and cannot include any markings or other information that might indicate the package contains medication. Each package must include a unique identification number or other unique identifier to enable tracking.

  Mail-back packages cannot be returned to the pharmacy. Instead, packages must be directly mailed

to a collector that is authorized by the DEA or other federal law to destroy medication. Consumers cannot be required to provide personally identifiable information when mailing back medication.

Medication may be accepted from any member of the public. However, collection receptacles or mail-back programs cannot be used to dispose of unused/unwanted medication in the pharmacy's inventory (e.g., expired medication, medical waste). Collected medication must be rendered non-retrievable and destroyed in compliance with all applicable federal and state laws. Destruction may occur at the pharmacy or destroyed offsite by an entity authorized by state/federal law to destroy medication. Destruction records and inventories of inner-liners must be maintained for two (2) years and available on inspection/request (*see rule for additional recordkeeping requirements*). Collected medication cannot be resold or reused under any circumstances.

Pharmacies are not required to establish a drug collection program and participation is voluntary. Participating licensees should review 20 CSR 2220-2.095 in its entirety to ensure compliance

20 CSR 2220-2.095 does not apply to medication collected for return and reuse as authorized by 20 CSR 2220-3.040. (Return & Reuse of Drugs and Devices)

CONTROLLED SUBSTANCES: Section 195.265 allows licensees to collect returned controlled substances for destruction. Controlled substances may only be returned as authorized by state and federal law. Interested licensees have to modify their existing BNDD and DEA registrations to become a collector. BNDD and DEA may have additional requirements. DEA take-back information is available online at: https://www.deadiversion.usdoj.gov/drug_disposal/index.html . BNDD compliance information is available on BNDD's website at https://health.mo.gov/safety/bndd/collection-disposal-info.php.

DRUGS DONATED FOR REUSE: The Missouri Department of Health and Senior Services ("DHSS") regulates the Prescription Drug Repository program. Additional information is available on DHSS' website at health.mo.gov/safety/drugrepository. Additional federal requirements may apply for individuals exporting medication to another country for reuse or charity purposes.

Questions regarding exporting medication should be addressed to the FDA's Import Export Compliance Branch (IECB) at CDERExportCertificateProgram@fda.hhs.gov. (See D.15 for medication donations to Class Q Charitable Pharmacies)

H.27 DISTRIBUTION VS. DISPENSING

Pharmacies may sell or transfer legend drugs or a drug-related device to another pharmacy or to an authorized prescriber/entity by invoice (schedule III-V drugs/non-controlleds) or via CSOS or a DEA 222 form (schedule II drugs). Except as allowed by law, prescriptions cannot be used to transfer medication for prescriber or facility use. Invoices must be maintained in the pharmacy's records separately from prescription records and must include:

1. The distribution date;
2. Product name/strength;
3. Quantity;
4. The names/address of the parties; and
5. If a controlled substance, DEA numbers for both the transferring pharmacy and the recipient.

Controlled substance transfers must comply with federal/state controlled substance laws. Pharmacies may not repackage drugs for distribution to other pharmacies or practitioners without being registered with the

FDA as a repackager. *See D.10 for Class-B exemptions.*

A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross sales. Total gross sales are calculated based on the pharmacy's total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy's total purchases. [§ 338.330(2); 20 CSR 2220-5.020(1)(B)]. *See D.10 for Class-B exemptions.*

> *Pharmacies that "borrow" or "loan" medication between themselves must maintain a record of the transactions (invoice/DEA-222). In a borrowing and payback scenario, the pharmacy must have two transaction records: one record documenting receipt of the products and one record documenting the return of the product. The same documentation must be maintained by the pharmacy loaning the product. Intra-store transfers must also be recorded/documented. See D.9 for transferring medication when a pharmacy closes.*

H.28 AUTOMATED FILLING SYSTEMS [20 CSR 2220-2.950]

Rule 20 CSR 2220-2.950 establishes requirements for pharmacists using an automated filling system (AFS) to dispense prescriptions. An AFS is defined as *"an automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling or sealing medication for dispensing."* An AFS does not include:

1. Automated devices used solely to count medication (counting devices),
2. Vacuum tube drug delivery systems governed by 20 CSR 2220-2.800, or
3. Automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to a patient.

A pharmacist must inspect and verify the contents and label of every prescription filled by an AFS unless:

- A pharmacist verifies the accuracy of the prescription data used by or entered into the AFS for the specific patient prior to filling. The identity of the verifying pharmacist must be documented in the pharmacy's records and maintained for five years [20 CSR 2220-2.950(4)(C)]; and
- A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was loaded in the AFS before initiating the fill process. [20 CSR 2220-2.950(4)(D)]. An electronic verification system may be used to verify manufacturer unit of use packages or repacked medication previously verified by a pharmacist. Repacked containers must comply with 20 CSR 2220-2.130; and
- The filling process is fully automated from the time the process is initiated until a completed prescription is produced that is ready for dispensing to the patient. [20 CSR 2220-2.950(4)(B)]. In other words, the AFS must either fill, label, and seal the prescription in the container or the prescription must be dispensed by the AFS in a manufacturer's unit of use package or a repacked pharmacy container. [20 CSR 2220-2.950(4)(E)]. No manual intervention with the medication or prescription may occur after the medication is loaded into the AFS. Pharmacy staff may prepare or package the final labeled product container for mailing, storage or delivery. However, no other manual intervention is allowed; and
- An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient [20 CSR 2220- 2.950(4)(F)] ; and;*
- Daily random quality testing is conducted by a pharmacist on at least two percent (2%) of the prescriptions filled by the AFS on the date tested or 2% of the prescriptions filled by the AFS on the last day of system operation. The pharmacist-in-charge must determine how the sample is selected. Proof of compliance, random quality testing date(s), and testing results must be documented and maintained

in the pharmacy's records and available for inspection. [20 CSR 2220-2.950(4)(G)]

** Electronic verification systems must comply with 20 CSR 2220-2.950(1)(B). Video/camera verification systems alone do not qualify as electronic verification systems.*

Significantly, pharmacies using an AFS in lieu of physical pharmacist verification must test the system before initial use, when restarting the system or after any modification to the AFS or electronic verification system that may change or alter the filling/electronic verification process.

Pharmacies using an AFS in lieu of physical inspection/verification of the final product by a pharmacist must maintain written policies and procedures to monitor and ensure the AFS is functioning properly and safely. 20 CSR 2220-2.950(5) contains a detailed listing of minimum policy/procedure requirements. Policies/procedures must address:

- System maintenance
- Accurate loading
- Sanitation, cross-contamination
- Expired/recall drugs
- Errors and malfunctions
- Testing
- Training
- System access
- Tracking responsible persons
- Quality assurance

AFS policies and procedures must be reviewed annually and maintained in the pharmacy's records for at least two (2) years.

> *The required AFS policies and procedures and mandatory testing only apply if a pharmacist is not physically inspecting and verifying the final product. Pharmacies physically verifying the final contents and label of medication filled or packaged by an AFS are not subject to the additional requirements of 20 CSR 2220-2.950(4) – (6).*

H.29 EPINEPHRINE/ASTHMA MEDICATION

School Districts: Section 167.630, RSMo, authorizes Missouri school districts to obtain prefilled epinephrine auto syringes by prescription. Section 167.635 contains the same allowance for asthma related rescue medications. To obtain prefilled epinephrine auto syringes or asthma related rescue medications, a prescription is required from a licensed physician, a physician's assistant, or nurse practitioner. The school district must be designated as the patient and the school nurse's name must be on the prescription. Pharmacies may legally dispense prescriptions that comply with § 167.630 or § 167.635.

Authorized Entities: Section 196.990, RSMo, also authorizes pharmacists to dispense epinephrine auto-injectors to an "authorized entity" based on a prescription issued by a Missouri licensed physician in the name of the authorized entity (e.g., Jefferson City Parks and Recreation). An "authorized entity" is defined as:

> *Any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, qualified first responders, as such term is defined in section 321.621, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;*

A qualified first responder under § 321.621, includes any state or local law enforcement agency, fire department, or ambulance service that provides documented training to its staff on administering epinephrine auto-injector devices in an apparent anaphylactic reaction.

Only a Missouri licensed physician may issue an epinephrine prescription to an authorized entity under § 196.990. The prescription may not be written by a mid-level practitioner. Once written, prescriptions are

valid for 12-months and may be refilled as needed unless otherwise restricted by the physician. Quantity limits are as prescribed. The prescription must be maintained and documented in the same manner as other non-controlled prescriptions.

Section 196.990.4 contains mandatory training requirements for "expected auto-injector users" who may be administering or providing epinephrine to the public on behalf of an authorized entity. It appears the additional training requirements only apply to users that acquire epinephrine auto-injectors under a prescription issued in accordance with § 196.990.

The Board has been asked if pharmacists can provide the required training for auto-injector users. The statute provides:

> *Expected epinephrine auto-injector users [must] receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services.*

Licensees should contact the Missouri Department of Health and Senior Services for questions on becoming an approved trainer.

Pharmacists filling an epinephrine prescription for an authorized entity under § 196.990 do not have to complete additional training.

H.30 MEDICAL MARIJUANA

Medical marijuana is regulated by the Missouri Department of Health and Senior Services (DHSS). DHSS has established an online medical marijuana information portal at https://health.mo.gov/safety/medical-marijuana/. Questions regarding medical marijuana should be addressed to DHSS. The Board does not have jurisdiction over medical marijuana and cannot answer questions or provide guidance.

Licensees have asked if pharmacists can own, advise, or consult with a medical marijuana dispensary/cultivator. Licensees should consult with legal counsel on this issue- the Board cannot provide legal advice. However, the DEA had advised that federal controlled substance registrants are required to comply with federal law which still designates marijuana as a C-I controlled substance.

I.1 GENERAL REQUIREMENTS

A Class D (Non-Sterile Compounding) pharmacy permit is required for pharmacies performing non-sterile compounding in batch quantities using bulk active ingredients. Rule 20 CSR 2220-2.400 defines compounding as:

> *The preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding also includes the preparation, incorporation, mixing, and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.*

A Class-H (Sterile Compounding) pharmacy permit is required for pharmacies performing sterile compounding. (*See Section J for sterile compounding requirements).*

The Board does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (e.g., Benzaclin®, Benzamycin®, Epaned® etc.). However, the use of compounding kits that include the compounding ingredients is considered compounding and requires compliance with the Board's compounding rules, including, completion of the compounding log (e.g., First® Kits).

Pharmacies may not compound preparations that have been withdrawn from the market due to safety.

- *As defined by the Board's rules, compounding does not include incorporating a flavoring agent. However, licensees should indicate that the product was flavored on the patient container and the added flavoring must be documented in the prescription record. (See section H.14 for additional information on flavoring)*
- *The Board has not addressed if or how it will adopt or enforce USP Chapter 800 Hazardous Drugs- Handling in Healthcare Settings. However, compliance with USP Chapter 800 may be required by other entities (e.g., accrediting agencies, insurers, etc.). Licensees should consult with legal counsel to determine how USP Chapter 800 will affect your practice.*

I.2 PRESCRIPTION REQUIREMENTS/ COMPOUNDING FOR OFFICE USE

Except as otherwise provided by law, licensees may only dispense compounded preparations pursuant to a valid prescription or a medication order *(see veterinary exception below)*. Compounded preparations may not be offered to pharmacies, practitioners or commercial entities for office use or for subsequent resale. [20 CSR 2220-2.400(12)] However, pharmacies/pharmacists may dispense a compounded preparation for a prescriber to administer in the prescriber's office if a valid prescription or medication order has been received for the individual patient. Please consult BNDD/DEA if a controlled substance is involved.

Compounding may only be done by prescription/medication order, regardless of the type of product (e.g., OTC, herbal). [20 CSR 2220-2.400(10)].

An FDA registered drug manufacturer or a 503(b) drug outsourcing facility may provide compounded preparations for office use, provided the entity is also licensed as a Missouri drug distributor (manufacturers) or a Missouri outsourcer (503(b) drug outsourcing facilities).

Veterinary Exception: Pursuant to 20 CSR 2220-2.400(13), pharmacies may provide non-patient specific compounded preparations to a Missouri-licensed veterinarian to administer and dispense to the

veterinarian's animal patients, provided the pharmacy complies with all controlled substance laws and maintains a record of distribution to the veterinarian that can be retrieved by the specific veterinarian. A prescription from the veterinarian is not required to distribute office stock supply.

Non-patient specific preparations dispensed to a veterinarian under 20 CSR 2220-2.400(13) must be labeled with:

- The pharmacy's name, address and telephone number,
- Date of distribution *(the Board also recommends documenting the distribution date in the pharmacy's records)*;
- Veterinarian's name;
- Preparation name, strength, dosage form and quantity;
- Name of each active or therapeutic ingredient included in the preparation;
- Preparation lot/batch number;
- Preparation beyond-use date;
- The statement: "Office Stock Compounded Preparation."

Additionally, the preparation must be recorded in the pharmacy's compounding log as required by 20 CSR 2220-2.400(7) (A). In lieu of a prescription number or a readily unique identifier, the veterinarian's name may be recorded in the compounding log.

Licensees should be aware that Missouri Veterinary Board rule 20 CSR 2270-4.031(3)(H) provides:

> *A veterinarian may dispense no more than a seven (7) day supply per patient from an office stock compounded preparation provided by a licensed pharmacy. A patient-specific prescription must be issued to continue treatment beyond seven (7) days…*

The veterinarian supply limit is not enforced by the Board; Questions should be addressed to the Missouri Veterinary Board at (573) 751- 0031 or vets@pr.mo.gov (e-mail is preferred).

This exemption only applies to preparations provided to a Missouri-licensed veterinarian. Compounding for veterinary office stock is not allowed if the receiving veterinarian is not a Missouri licensed veterinarian.

I.3 ANTICIPATORY COMPOUNDING

Medication may be compounded in "limited quantities" prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [20 CSR 2220-2.400(7)(C)]. For purposes of 20 CSR 2220-2.400, a "limited quantity" is defined as a three (3) month supply of a batched product, or a one (1) year supply for compounded preparations intended for external use (e.g., creams, ointments, lotions or liniments). While advance preparation is allowed, a prescription is required for dispensing.

I.4 COMMERCIALLY AVAILABLE PRODUCTS

Generally, Missouri law prohibits licensees from compounding preparations that are commercially available or that are essentially copies of commercially available products. "Essentially copies" includes different dosage forms (e.g., suspension vs. solution, tablet vs. capsule). The Board reviews multiple factors when determining if a preparation is essentially a copy of a commercially available product, including if use of a commercially available product will provide the same drug and dose (1ml of a compounded 120mg/ml vs. 1.2ml of a commercially available product). A different formulation alone does not make a preparation not an essential copy (sesame seed oil vs. peanut oil).

Licensees may only compound a commercially available product if:

1) The product is temporarily unavailable due to problems other than safety or effectiveness (e.g., on back order). Unavailability must be documented in the pharmacy's records. [20 CSR 2220-2.400(9)]. The Board recommends keeping any documentation from the manufacturer/distributor or the FDA Drug Shortage database, including, documentation of the dates the product was unavailable. The pharmacy must stop compounding the product once the product becomes available again; or
2) A "specific medical need" for the prescription exists. [20 CSR 2220-2.400(9)]. The "specific medical need" is deemed to be the *medical reason* why the commercially available product cannot be used. The nature of the "specific medical need" must be either documented on the prescription/medical order or some other documentation of the specific medical need must be noted in the pharmacy's prescription records. [20 CSR 2220-2.400(9)]. Notations should include the name of the person verifying the medical need, the date, and the specific medical need/reason given. Cost or convenience are insufficient to establish a "specific medical need." A prescription that only identifies a patient name and compounded preparation formulation is insufficient documentation.

The Board does not consider compounding kits that include compounding ingredients to be commercially-available; A pharmacy may still compound these preparations without using the kit. However, if a specific compounding kit is prescribed, a pharmacist would need prescriber's authorization to compound without using the kit.

I.5 PRODUCT VERIFICATION

The dispensing pharmacist must ensure compounded preparations are properly prepared, labeled, stored, dispensed, and distributed. [20 CSR 2220-2.400(8)] Before release, the pharmacist must visually inspect bulk drug substances and all finished products for container closure integrity, visible particulates, and other foreign matter/visual defects.

For quality purposes, the dispensing pharmacist must also ensure that:

1) Each person assisting in compounding is capable and qualified to perform their assigned duties;
2) All ingredients have their expected identity, quality, and purity;
3) Reasonable assurance exists that compounding processes/procedures are always carried out by pharmacy staff as intended or specified; and
4) Compounding conditions/procedures are adequate for preventing mix-ups or other errors.

The Board has observed several instances of pharmacists compounding with expired ingredients. In many instances, the expired date was recorded in the compounding log signed by the pharmacist. Pharmacists should review all log entries for accuracy. Additionally, expired medication must be quarantined in a clearly marked area that is physically separated from the active inventory. [20 CSR 2220-2.010(2)(B)].

I.6 LABELING

In addition to other prescription labeling requirements, the actual name of each active or therapeutic ingredient contained in a compound must be listed on the patient's prescription container or on an auxiliary label [20 CSR 2220-2.400(7)(F)]. Auxiliary labels may be electronically generated/printed or even hand-written, if legible.

Ingredient abbreviations are not sufficient. For example, "Melox, Topir, Tram, Lido, Prilo" should be listed as

"Meloxicam, Topiramate, Tramadol, Lidocaine, Prilocaine" on the container. If the computer system's drug field has limited character space, an auxiliary label applied to the container may be the best option to allow for the full names.

Additionally, compounding labels must identify the actual ingredient used. This means a specific brand name product should not be listed if a generic was used in the compound (i.e., "Maalox" should not be listed if a generic version was used). Additionally, ingredient labeling should not be over generalized (e.g., "antacid" is ambiguous and does not identify which product was used).

The Board's inspectors have observed a number of violations in this area. Review your compounding procedures and educate staff to ensure compliance with required labeling

I.7 BEYOND-USE DATES

Batched compounded preparations must be assigned an in-house batch/lot number and a "beyond-use date" after which a compounded preparation should not be used. [20 CSR 2220-2.400(7)(A)6.] Licensees should use their professional judgment when determining the appropriate beyond-use dates. Because compounded preparations are intended for immediate administration or following short-term storage, beyond-use dates must be assigned based on different criteria than those used to assign an expiration date for manufactured drug products. [20 CSR 2220-2.400(4)]. Licensees may be asked to explain or support their rationale. Beyond-use dates must be determined from the date the preparation is compounded.

Compounds that are not picked up by the patient and returned to stock are considered batched and must be assigned a batch number and a beyond-use date in the compound log and on the label.

I.8 INGREDIENTS/CONTAINERS [20 CSR 2220-2.400(6)]

Proper controls must be maintained over drug products/ingredients, containers and container closures to prevent contamination. Drug components must meet compendial standards (e.g., USP, NF). If non-compendial bulk drug substances are used, a certificate of analysis must be kept on file. [20 CSR 2220-2.400(8)2.] Non-drug substances must be contaminant free and maintain full potency.

Container systems must be stored and used in a manner that will adequately protect against foreseeable deterioration or contamination. Drug products, ingredients, containers and container closures may not be reactive, additive or absorptive in any way that would alter the safety, identity, strength, quality or purity of the compounded preparation beyond the desired result.

Compounding materials and preparation must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Excess products must be labeled with the name of the drug(s), an in-house lot number, and the beyond-use date, and must be stored and accounted for under conditions dictated by their composition and stability. [20 CSR 2220-2.400(6), (7)].

- *For bulk ingredients that don't bear an expiration date, the pharmacy is encouraged to contact the manufacturer to determine the actual expiration date. If one is not provided, the pharmacy is encouraged to develop procedures for establishing an in-house expiration date for the ingredient.*

Federal requirements are stricter than Missouri's regulations when compounding with bulk drug substances. See the below excerpt from FDA's website on 503A pharmacy compounding:

Bulk drug substances	Bulk drug substance must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with FDA under section 510. In addition, the bulk drug substance must comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if one exists, and the USP chapter on pharmacy compounding; if an applicable USP/NF monograph does not exist, be a component of an FDA-approved drug; or if such a monograph does not exist and the substance is not a component of an FDA-approved drug, appear on a list of bulk drug substances that can be used in compounding under section 503A developed by FDA through regulations.

I.9 FACILITIES/EQUIPMENT [20 CSR 2220-2.400(5)]

Compounding area(s) must be clean and sanitary at all times and free of infestation. Trash must be disposed of in a timely manner.

Additionally, compounding equipment must be adequately and appropriately designed for the activities performed. Equipment surfaces may not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired. [20 CSR 2220-2.400(6)(E)]. Equipment must be appropriately located to allow for proper use, cleaning and maintenance. [20 CSR 2220-2.400(5)(C)].

If drugs with special contamination precautions are used (e.g., penicillin), appropriate measures must be utilized to prevent cross-contamination. [20 CSR 2220-2.400(5)(B)]. Appropriate measures may include, but may not be limited to, dedicating or adequately cleaning equipment.

I.10 COMPOUNDING LOG

Pharmacies must maintain a separate compounding log that includes [20 CSR 2220-2.400(7)(A)]:

1) The compounding method used;*
2) The compounding date;
3) Identity of the compounding pharmacist;
4) A listing of the drug products/ingredients and their amounts by weight or volume;
5) Description of the compounding process and, if necessary for proper compounding, the order of drug product/ingredient addition (e.g., recipe/formula cards);*
6) The source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded preparations; and
7) A prescription number or a readily retrievable unique identifier for the compound. All prescription numbers/identifiers dispensed from a batch compound must be recorded individually on the compounding log. Pharmacies compounding non-patient specific preparations for a Missouri-licensed veterinarian for administration/dispensing to the veterinarian's animal patients as authorized by 20 CSR 2220-2.400(13) may record the veterinarian's name in lieu of a prescription number/unique identifier)

** May be separately stored in the pharmacy's records if the records are immediately retrievable.*

I.11 QUALITY CONTROL

Pharmacies must establish and maintain appropriate quality control measures over compounding methods. [20 CSR 2220-2.400(7)] Quality control measures must include:

1) Methods for compounding to ensure finished preparations have the identity, strength, quality and purity they purport or are represented to possess, and;

2) A description of the compounding process and the order for adding drug products/ingredients, if applicable.

Additionally, pharmacies must develop and maintain an outcome related drug monitoring system for evaluating the quality of compounding services. At a minimum, the monitoring system must evaluate/track infection rates, adverse drug reactions, recalls, and prescriber/client complaints.

I.12 RECALLS

A recall must be initiated if a compounded preparation is deemed to be misbranded or adulterated. [20 CSR 2220-2.400(8)(C)]. In the event of a recall, the pharmacy must notify the prescriber of: 1) the nature of the recall, 2) the problem(s) identified, and 3) any recommended action(s). If the compounded preparation could potentially cause patient harm, the same recall notification must be provided to the patient. Notification can be made verbally, electronically, or in writing, however, licensees should use their professional judgment to determine the best way to effectively alert the prescriber or the patient. For example, a mailed letter may be inappropriate if immediate action is needed. The Board recommends that licensees retain proof of the date and manner of the required recall/notification in the pharmacy's records.

In addition to prescriber/patient notification, recall(s) must be reported to the Board in writing within three (3) business days.

I.13 ADVERTISING/SOLICITATION

Licensees may advertise or provide information regarding compounding services and the type of compounding offered. However, licensees may not compare compounded preparations to commercially available products or make specific claims without supporting data (e.g., designating a product as sustained release). [20 CSR 2220-2.400(12)]. Alternatively, licensees may not attempt to solicit business by making specific claims about compounded preparations without analytical data to support the claims for each compounded preparation. Licensees must have data for their specific preparations and may not rely on data obtained from other sources.

I.14 REPORTING OF COMPOUNDING DATA

The Federal Drug and Cosmetic Act (FDCA) provides drug products dispensed or distributed in the U.S. must comply with federal requirements related to:

1. Current good manufacturing products (cGMP),
2. Labeling with adequate directions for use, and
3. FDA approval before marketing. [See FDCA section [503(A)]

The FDCA exempts pharmacists and physicians from cGMPs, designated labeling requirements and FDA approval, if:

1. The pharmacy is in a state that has entered a compounding Memorandum of Understanding (MOU) with the FDA, or;
2. If the pharmacy's home state has not signed the MOU, the number of compounded products shipped interstate by the pharmacy/physician does not exceed 5% of the total prescription orders dispensed or distributed by the pharmacy or physician. [See FDCA section [503(A)]

In October 2020, the FDA adopted a federal/state Memorandum of Understanding Addressing Certain

Distributions of Compounded Human Drug Products. The Board approved signing the FDA MOU in April 2020, and subsequently promulgated rule 20 CSR 2220-2.425 (Required Pharmacy Reporting), which addresses reporting of needed compounding data to comply with MOU requirements.

A third-party federal lawsuit was filed in 2021 challenging designated MOU provisions. The FDA subsequently announced in February 2022 that it intends to undertake the federal rulemaking process and stayed enforcement of the MOU pending final rulemaking.

In light of the FDA's stayed enforcement, the Board will be exercising its enforcement discretion and will extend enforcement of 20 CSR 2220-2.425 until January 31, 2024. Pharmacies do have to file their initial compounding data reports required under 20 CSR 2220-2.425 until January 31, 2024. The 2024 report will cover 2023 compounding data. The Board recommends that pharmacies begin collecting/tracking required compounding data now to meet the 2024 deadline. *Note: Licensees should monitor the Board's website for updates on the Board's enforcement date.*

Required Reporters: Except as listed below, 20 CSR 2220-2.425 is applicable to all pharmacies located in Missouri that are compounding human drug preparations, even if the pharmacy is not compounding from bulk ingredients, does not have a Missouri Class D (Non-Sterile Compounding) or Class H (Sterile Compounding) pharmacy permit, or does not dispense/distribute compounded preparations outside of Missouri.

- 20 CSR 2220-2.425 only applies to pharmacies located in Missouri and does not apply to non-resident pharmacies *(other home state laws may apply)*.
- *Hospital Applicability:* 20 CSR 2220-2.425 applies to entities under the Board's jurisdiction. The Board does not have jurisdiction over medication compounded by a Missouri licensed hospital under the Missouri Dept. of Health and Senior Services' jurisdiction, for administration to the patient within the "licensed premises" of the hospital. However, pharmacy compounding under the Board's jurisdiction would need to be reported to the Board.

Reporting Requirements: Pharmacies have to report the following compounding data to the Board annually:

A. The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy distributed or dispensed interstate during the previous calendar year;
B. The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy dispensed (or caused to be dispensed) from the facility in which the drug preparations/products were compounded during the previous calendar year (e.g., not picked up on-site by the patient or the patient's designee);
C. The number of prescription or medication orders for compounded human drug preparations/products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up by the patient or the patient's designee);
D. The sum of the figures from (A) and (B) above; and
E. The quotient from dividing the figure in (A) by the figure from (D).

If the figure from section (E) above is greater than five tenths (0.5), the pharmacy must also report:

A. The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;
B. A list of the states where the pharmacy was licensed during the previous calendar year; and

C. A list of the states into which the pharmacy distributed compounded human drug preparations/products during the previous calendar year.

According to FDA Guidance, the MOU does not apply to:

- Drugs intended for veterinary use
- Repackaged drug products *(The Board's rules would require reporting of repackaged compounded sterile preparation data)*
- Radiopharmaceuticals
- Biological products subject to licensure under section 351 of the Public Health Service Act, or
- Drugs compounded by outsourcing facilities under section 503B of the FD&C Act.

Pharmacies do not have to report compounding data to the Board for the products/preparations listed above. [See also 20 CSR 2220-2.425(4) and/or FDCA Section 503(A)]

Additionally, the Board does not consider flavoring a prescription to be compounding. The Board also does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (e.g., Benzaclin®, Benzamycin®, Epaned® etc.). However, the use of compounding kits that include the compounding ingredients is compounding and would fall under 20 CSR 2220-2.425's reporting requirements (e.g., First® Kits).

Compounding data reports can be manually or electronically submitted to the Board office; A sample reporting form will be available on the Board's website prior to January 2024.

Alternatively, pharmacies may electronically report compounding data to the Board via the National Association of Boards of Pharmacy's (NABP) Information Sharing Network. NABP's Information Sharing Network is currently a free electronic data exchange operated by NABP for collecting required pharmacy MOU data. Visit NABP's website for NABP registration and technology requirements. Pharmacies may begin voluntarily reporting to NABP's Information Sharing Network now and do not have to wait until 2024.

- 20 CSR 2220-2.425's reporting requirements and calculations were taken from the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. To ensure consistency, the Board did not make any substantive changes to the MOU requirements.

J.1 GENERAL REQUIREMENTS

**Section J contains a brief overview of changes to the sterile compounding rule. Licensees should review 20 CSR 2220-2.200 in its entirety to ensure compliance with Missouri's sterile compounding requirements.*

A Class-H (Sterile Compounding) pharmacy permit is required for all pharmacies performing sterile compounding. Class H pharmacies must comply with all applicable provisions of state/federal law, including rule 20 CSR 2220-2.200 governing sterile compounding and 20 CSR 2220-2.400 which establishes standards of practice for both non-sterile and sterile compounding. Compliance with 20 CSR 2220-2.200 and 20 CSR 2220-2.400 is mandatory for all pharmacies holding a Class H Sterile Compounding pharmacy permit even if the pharmacy is not currently providing sterile compounding services.

The Board has not adopted USP Chapter 797 at this time, however, USP's recent revisions are currently under review. Interested parties should monitor the Board's website for updates.

J.2 COMPOUNDING DEFINITIONS

The following major definitions are included in 20 CSR 2220-2.200:

	DEFINITIONS
Buffer area	An ISO Class 7 or better area where the primary engineering control (PEC) is physically located. The terms "clean room" and "clean zone" have been deleted throughout the rule
Class 100/ Class 10,000 area	No longer used. The current rule references ISO Class 5 or ISO class 7 area to match current ISO classifications.
Controlled Area	A separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.
Isolator/Barrier Isolator	See "Restricted Access Barrier System"
Primary Engineering Control (PEC)	A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but are not limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, or a restricted access barrier system (RABS). All sterile compounding must occur in a PEC or in an ISO Class 5 environment.
Restricted Access Barrier System	A PEC that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of

	contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a compounding aseptic isolator (CAI) or a compounding aseptic containment isolators (CACI). **Note: The Board's rules no longer reference an "isolator" or "barrier isolator." These terms have been deleted and changed to a "restricted access barrier system" or "RABS" as defined above.*

J.3 COMPOUNDING RISK LEVELS

Rule 20 CSR 2220-2.200 establishes the following compounding risk levels:

RISK LEVEL	AMENDED RULE
Risk Level 1	• Preparations stored at controlled room temperature and assigned a beyond- use date of 48 hours or less • Preparations stored under refrigeration and assigned a beyond-use date of 7 days or less • Preps stored frozen and assigned a beyond-use date of 30 days or less
Risk Level 2	• Preparations stored at controlled room temperature and assigned a beyond- use date greater than 48 hours • Preparations stored under refrigeration and assigned a beyond-use date greater than 7 days • Preparations stored frozen and assigned a beyond-use greater than 30 days • Batch prepared preparations without preservatives that are intended for use by more than 1 patient • Preparations compounded by complex or numerous manipulations (e.g automated compounder)
Risk Level 3	• Products compounded from nonsterile ingredients or compounding with nonsterile components, containers or equipment before terminal sterilization • Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

J.4 COMPOUNDING IN CONTROLLED AREAS

In lieu of an ISO classified buffer area, the sterile compounding rule allows licensees to compound sterile preparations in a PEC that is located in a "controlled area." The controlled area does not have to be a separate room. Instead, a controlled area can be a separate room or an area of the pharmacy that is clearly separated from other pharmacy activities/ operations by a line of demarcation. *NOTE: Risk Level 2 and 3 preparations can only be compounded in a controlled area if a RABS is used.*

Controlled areas must be designed and maintained to allow effective cleaning and disinfection as required by the rule (see cleaning chart below). A sink with hot and cold running water must be near, but not in, the

controlled area. Traffic flow in or around the controlled area must also be minimized and controlled to prevent contamination. Non-essential objects that shed particles cannot be brought into the controlled area (e.g., cardboard, paper towels, cotton gauze, etc). Significantly, pharmacy staff compounding in a controlled area must be garbed as required by the rule for all risk levels *(see garbing chart below)*. Pharmacy and cleaning staff must be educated and instructed on how to properly garb.

J.5 GARBING REQUIREMENTS

RISK LEVEL	REQUIRED GARB
Risk Level 1	*Non-shedding gown, hair cover, face mask, beard cover and gloves*
Risk Level 2	*Non-shedding gown, hair cover, face mask, beard cover, shoe covers, and sterile gloves*
Risk Level 3	*Non-shedding gown, hair cover, face mask, beard cover, shoe covers, and sterile gloves*

All personnel entering the controlled or buffer area must be garbed appropriately. If a RABS is used for risk level 2 & 3 compounding, sterile gloves must be donned over RABS gloves.

J.6 TRAINING REQUIREMENTS & MEDIA FILL TESTING

Education and training of compounding staff is a vital part of maintaining sterility and preventing contamination. The sterile compounding rule requires that all pharmacy personnel receive suitable didactic and experiential training prior to compounding. Additionally, all compounding staff must complete and pass an initial and ongoing aseptic technique skill assessment with media fill testing. The required aseptic technique skill assessment must include a direct visual observation/evaluation of aseptic competency during a process simulation (media fill test). The media fill test must represent the most challenging or stressful conditions that the individual encounters or performs (e.g., the highest risk or batch process).

All sterile compounding personnel must complete and pass an initial assessment prior to compounding. A minimum of three media-fill tests must be completed during the initial assessment. The frequency of re-assessment differs based upon the risk level of compounding (see below). One media fill test must be completed for the ongoing testing.

- Risk Level 1: Prior to compounding and annually thereafter
- Risk Level 2: Prior to compounding and annually thereafter
- Risk Level 3: Prior to compounding and every six months thereafter

The visual observation portion of the aseptic technique skill assessment must include the following competencies:

- Proper aseptic technique, including use of first air and avoiding touch contamination
- Cleaning and disinfection
- Hand hygiene, garbing, and gloving
- Identifying, weighing and measuring of ingredients
- Maintaining sterility in ISO Class 5 areas, and
- Labeling and inspecting compounded sterile preparations for quality

Individuals who fail any written test, media fill test, or visual observation of hand hygiene, garbing or aseptic technique must be retrained and pass a reevaluation in the deficient area before beginning or resuming

sterile compounding. Individuals who fail media-fill testing must pass three (3) successive media fill tests prior to resuming sterile compounding. Training dates and testing/re-testing results must be documented in the pharmacy's records.

Media fill testing must be conducted in accordance with USP Chapter 797 and as referenced below:

Frequency of media fill testing	• *Before compounding** • *If the quality assurance program yields an unacceptable result or unacceptable techniques are observed* • *If the staff's risk level of sterile compounding changes (e.g., staff begins compounding risk level 3)* • *If there is a change in compounding methods*
Frequency of media fill testing re- evaluation	• *Risk level 1 & 2 (annually)** • *Risk level 3 (every 6 months)**
# of media fill tests	• *Initial training (3 media fill tests)* • *Ongoing reassessments (1 media fill test)*

**As part of the required aseptic technique skill assessment*

Emergency Aseptic Technique Skills Assessment Allowance:

If needed to prevent interruptions in patient care during an emergency, a pharmacy may accept skills assessment results from another pharmacy or hospital in lieu of the required initial aseptic technique skill assessment, provided the following are met:

- A pharmacist verifies the skill assessment from the other pharmacy or hospitals meets the requirements listed above,
- The individual has received training at the current facility on applicable pharmacy operational procedures as needed to ensure proper compounding,
- The pharmacy maintains documentation of the skill assessment conducted at the other pharmacy/hospital, including the dates and results of the required training, testing, and observation(s),
- The pharmacy maintains a copy of the other facility's policies and procedures on aseptic skills assessments and media-fill testing, and
- After 45 days, the individual must complete an initial skills assessment at the current facility.

[20 CSR 2220-2.200(10)(E)]

Licensees are reminded that individuals must be skilled and trained to accurately and competently perform sterile compounding duties, regardless of where the skill assessment occurred. [20 CSR 2220-2.200(10)(E)]

The emergency allowance should not be used to address routine or foreseeable staffing issues. Instead, emergencies should be limited to instances where additional staff is needed to meet urgent patient care needs or to prevent serious adverse medical consequences.

J.7 CLEANING AND DISINFECTION

Controlled areas and buffer areas must be cleaned and disinfected in accordance with USP Chapter 797. This would include the following requirements for all risk levels:

AREA	FREQUENCY OF CLEANING/DISINFECTION
ISO Class 5 primary engineering control(s)	• *Daily cleaning: Germicidal cleaning agent followed by sterile alcohol* • *Frequent disinfection throughout the day using sterile alcohol (includes prior to compounding, between batches and after spills/surface contamination)*
Counters & work surfaces	• *Daily*
Floors	• *Daily*
Walls	• *Monthly*
Ceilings	• *Monthly*
Storage shelving/supply bins	• *Monthly*

- All cleaning tools must be low-lint and dedicated for use in the controlled or buffer area
- Sterile water for irrigation must be used for dilution of germicidal agents that will be used in the primary engineering control
- If compounding occurs less frequently than the required timeframes, cleaning/disinfection must occur prior to each compounding session
- Individuals performing cleaning and disinfection shall be trained prior to performing such activities. Training must include direct visual observation of the individual's cleaning and disinfection process by qualified staff. The individual must be annually reassessed for competency through direct visual observation.

J.8 ENVIRONMENTAL SAMPLING

All sterile compounding pharmacies must establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in ISO classified areas. The following environmental sampling is required:

RISK LEVEL	FREQUENCY/TYPE OF ENVIRONMENTAL SAMPLING
Risk level 1	• *Air sampling* of all ISO classified areas before initial compounding and then every 6 months*
Risk level 2	• *Air sampling* of all ISO classified areas before initial compounding and then every 6 months* • *Surface sampling of all ISO classified areas every 6 months*
Risk level 3	• *Air sampling* of all ISO classified areas before initial compounding and then every 6 months* • *Surface sampling of all ISO classified areas every 30 days*

**Air sampling must be done via volumetric sampling. Settling plates are not sufficient*

In addition to environmental sampling for microbial organisms, all primary engineering controls and ISO classified areas must be certified to ensure facilities and equipment are operational. Hood and room certifications must be completed at the following frequencies:

- Prior to beginning any sterile compounding activities
- Every 6 months
- After any changes or major services occur to the primary engineering control or ISO classified area,

and

- After the primary engineering control or room is relocated or the physical structure of the ISO classified area has been altered

Hood and room certification results must be reviewed by a pharmacist once received (document the pharmacist review). Deficiencies or failures must be investigated and corrected prior to further compounding in the affected area.

J.9 END-PREPARATION EVALUATION

All final preparations must be inspected by a pharmacist to verify that the preparation was compounded accurately. This includes inspection for clarity, leaks, integrity, appropriate solution cloudiness or phase separation, solution color, and volume. Background light or other means for visual inspection of preparations must be used as part of the inspection process. Alternate means of inspection must be used if a visual inspection or exposure to the preparation may pose a health hazards (e.g., radiopharmaceutical). Additionally, risk level 3 preparations must be tested for sterility, endotoxins/pyrogens and potency as provided by the rule.

To ensure appropriate testing, the sterile compounding rule incorporates specific USP chapters for risk level 3 end-preparation testing.

- **Sterilization Methods**: Risk level 3 preparations must be sterilized using a method appropriate for the preparation and must be conducted in a method recognized by USP.
- **Sterility Testing**: All risk level 3 preparations must be tested for sterility according to USP Chapter 71. This is required for all risk level 3 preparations regardless of batch size and beyond use date.
- **Pyrogen/Endotoxin Testing**: All parenteral risk level 3 preparations must be tested for endotoxins/pyrogens according to USP Chapter 151 or 85. This is required for all risk level 3 parenteral preparations regardless of batch size and beyond use date.
- **Potency Testing**: All risk level 3 preparations assigned a BUD > 30 days must have laboratory validation of preparation stability and potency to support the BUD. Potency testing needs to be completed at least once. If the compounding methods change, potency testing must be completed again.

A compounded risk level 3 preparation may be dispensed prior to receiving the results of end product testing (referred to as emergency dispensing). This may occur when a risk level 3 preparation is needed for immediate administration and no alternative product or preparation is available. The prescriber must be informed that the preparation is being dispensed prior to the completion of appropriate testing. Documentation of the prescriber's approval for dispensing and the need for the emergency must appear in the prescription record. A separate authorization is required for each emergency dispensing (blanket authorization is not allowed)

J.10 REMEDIAL INVESTIGATIONS/RECALLS

All sterile compounding pharmacies must conduct a remedial investigation if any environmental monitoring sample demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling (e.g., air/surface sampling)

A remedial investigation would include quarantining the affected area and any sterile preparations/ingredients that were prepared or used within the compounding process until the results of

the investigation are known. Additionally, all affected areas must be re-sampled to ensure a suitable state of microbial control.

If an environmental monitoring sample taken from an ISO-5 classified area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected area until resampling shows a suitable state of microbial control. However, a pharmacy may choose to continue compounding during the remedial investigation if they do the following:

- Clean and disinfect the affected area by using a germicidal cleaning agent and a sporicidal agent followed by sterile alcohol, and
- The beyond-use date of all preparations is lowered to 12 hours, and
- The affected area is resampled under dynamic conditions. If the resampling exceeds USP 797 action levels, compounding must cease.

If an environmental monitoring sample taken from an ISO-7 classified buffer area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected area until resampling shows a suitable state of microbial control. However, a pharmacy may choose to continue compounding during the remedial investigation if they do the following:

- Clean and disinfect the affected area by using a germicidal cleaning agent and a sporicidal agent, and
- The beyond-use date of all risk level 1 preparations is lowered to 24 hours; the beyond-use date for all risk level 2 or 3 preparations is lowered to 12 hours, and
- The affected area is resampled under dynamic conditions. Compounding must cease if two consecutive re-samplings exceed USP 797 action levels.

Licensees must notify the Board in writing within three (3) days if any resamples collected as part of the remedial investigation exceed USP 797 action levels. Notifications should include details surrounding the remedial investigation, sampling results and any corrective actions taken. Notifications may be emailed to Katie.Debold@pr.mo.gov or mailed to the Board office. Maintain a record of all corrective actions taken during the remedial investigation including the resampling results.

Recalls: A recall must be initiated if a sterile preparation is deemed to be misbranded, adulterated, non-sterile or if end preparation testing results are out of specification. The following notifications must be made in the event of a recall:

- Prescriber: Must be notified of the nature of the recall, the identified problem(s) and any recommended actions
- Patient: Must receive the same notification as the prescriber if the preparation has the potential to harm the patient
- Board: Must be notified within 3 business days of the recall. Recall notices can be e-mailed to: Katie.DeBold@pr.mo.gov or mailed to the Board office *(**e-mail is preferred/requested**)*.

J.11 POLICIES & PROCEDURES

Pursuant to 20 CSR 2220-2.200(2), sterile compounding pharmacies must maintain a policy and procedure manual that addresses all aspects of sterile compounding performed by the pharmacy. Policy & procedure manuals should be regularly reviewed and updated to ensure appropriate practices. At a minimum, manuals must be reviewed annually. [20 CSR 2220-2.200(2)]. Policy and procedure manuals and documentation of the annual review will be required during inspection.

Board inspectors continue to observe instances of incomplete or outdated policy and procedure manuals. In other cases, pharmacy staff have not been updated or trained on recent changes. Manuals should be accessible to and reviewed by all pharmacy staff, including, new hires. Staff should be retrained when substantive changes are made or if there is a breach in aseptic technique.

J.12 NON-RESIDENT CLASS H STERILE COMPOUNDING PHARMACIES

Out-of-state pharmacies should be aware that the Missouri Board of Pharmacy has not adopted USP Chapter 797 but has regulation 20 CSR 2220-2.200 Sterile Compounding instead, which lists the requirements for sterile compounding. While the Board's requirements are similar to USP Chapter 797 in many respects, they are more stringent in the following:

- Risk level 3 (non-sterile to sterile) end-preparation evaluation – see Section J.9 above
- Remedial investigations/Recalls – see Section J.10 above

K.1 GENERAL REQUIREMENTS

Pharmacies are required to designate a primary record keeping system that may either be a non-electronic (manual) system or an electronic data processing system ("EDP"). [20 CSR 2220-2.010(2)]. All dispensing activities must be recorded in the designated system.

K.2 NON-ELECTRONIC (MANUAL) SYSTEMS

If a non-electronic record system is used, the pharmacy must maintain the following:

- A separate prescription file for Schedule I and II controlled substance prescriptions;
- A separate prescription file for Schedule III, IV and V controlled substance prescriptions; and
- A separate prescription file for all other non-controlled drug prescriptions. [20 CSR 2220-2.010(3)]

The following information must be maintained in a non-electronic system for each original and refilled prescription [20 CSR 2220-2.017]:

1. The date the prescription was prescribed and the date of initial dispensing, if different;
2. A sequential prescription label number or other unique identifier;
3. The name of the patient(s), or if an animal, species and owner's name;
4. The prescriber's name for oral prescriptions or signature for written or faxed prescriptions. Electronic signatures must comply with 20 CSR 2220-2.085;
5. For controlled substances, the prescriber's address, the patient's address, and the prescriber's DEA number;
6. Name, strength and dosage of drug, device or poison dispensed and the directions for use;
7. The number of refills authorized;
8. The quantity dispensed in weight, volume, or number of units;
9. The date of refill, if any;
10. The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;
11. The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;
12. Any change or alteration made to the prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug, and;
13. If additional refills are authorized and added to the prescription, a notation indicating the method and source of the authorization must be a part of the manual record or hard copy. The expiration date of the original prescription must remain the same. [20 CSR 2220-2.017(1)]

Prescriptions must be filed by the prescription number/unique identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017]. Poison sales may be recorded in a separate manual log. [20 CSR 2220-2.010(3)(A)]

K.3 ELECTRONIC DATA PROCESSING SYSTEMS (EDP) [20 CSR 2220-2.080]

If an electronic data processing system (EDP) is designated, the system must allow for the separate identification/ retrieval of Schedule II controlled substance prescriptions, the separate identification/retrieval of Schedule III-V controlled substance prescriptions, and the separate identification/retrieval of other non-controlled prescriptions. Required prescription hard copies must be stored in a three-file system as listed in

section K.2.

An EDP must be able to store and retrieve the following for each original and refill prescription:

1) A unique, sequential prescription label number;
2) If applicable, a unique readily retrievable identifier;
3) Date the prescription was prescribed;
4) The date the prescription was initially filled and the date of each refill;
5) Patient's full name, or if an animal, the species and owner's name;
6) The patient's address or animal owner's address, if a controlled substance has been prescribed;
7) The prescriber's full name.
8) For controlled substances, the prescriber's address and DEA #;
9) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
10) Quantity originally dispensed;
11) Quantity dispensed on each refill;
12) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
13) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
14) The number of authorized refills and quantity remaining;
15) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
16) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. If additional refills are authorized, the EDP system must indicate the method and source of authorization. [20 CSR 2220-2.080(2)]

Information may be entered into the EDP system by a licensed pharmacist or by a pharmacy technician or intern pharmacist working under the pharmacist's direct supervision. [20 CSR 2220-2.080(1)]. However, the pharmacist is personally responsible for the accuracy of inputted information. [20 CSR 2220-2.080(1)]. *See H.3 for remote data entry. Note: Poison sales may be recorded in a separate manual log. [20 CSR 2220-2.010(3)(A)]*

K.4 PRESCRIPTION HARD COPIES

Non-Controlled Prescriptions: Section 338.100, RSMo, requires that the "original order" of each drug must be maintained by the pharmacy for at least five (5) years. Accordingly, a physical hard copy of all non-controlled prescriptions must be maintained by the pharmacy unless the pharmacy has an electronic record-keeping system as described in Section K. 5. This requirement applies regardless of how the prescription was received (e.g., manually, faxed, scanned or electronic). Hard copies must be filed by the consecutive number or the unique identifier. A prescription hard copy is not necessary if the pharmacy maintains an image of the transmitted prescription data in a compliant electronic record-keeping system (see K.5).

Controlled Substances: State and federal controlled substance laws provide the following requirements:

TYPE	PHYSICAL HARD COPY REQUIRED?
Written	*Yes*
Faxed	*Yes*
Verbal/Telephone	*Yes*
Transferred	*Yes*
Electronically Prescribed	*Under federal law, a hard copy is not required. However, state law requires that either a hard copy or an image of the transmitted data must be maintained in an electronic record keeping system (see K.5 below)***

K.5 ELECTRONIC RECORD KEEPING SYSTEMS (ERS)

In lieu of a physical prescription hard copy, pharmacies that have an electronic record keeping system that complies with § 338.100, RSMo, may maintain a digitized image (scan) of a prescription. Rule 20 CSR 2220-2.083 defines an electronic record keeping system, or "ERS", as a system that provides "input, storage, processing, communications, output and control functions for digitized images of original prescriptions."

An electronic data processing system ("EDP") is different from an electronic record keeping system ("ERS"). To qualify as an ERS, the pharmacy's system must be able to capture "an exact digitized image" (scanned image) of the actual prescription, including, the reverse side of the prescription, if applicable. Simply transferring or electronically recording prescription data is insufficient. Pharmacies that do not have a compliant ERS must still maintain a physical prescription hard copy.

Digitized prescription images in an ERS must be readily retrievable and capable of being provided or reviewed immediately or within (2) hours of a request from the Board or a Board inspector. To prevent loss, digitized images in the ERS must be stored, copied or saved onto secure storage media on a regular basis. Pharmacies with an ERS must maintain a written policy and procedure manual that includes policies/procedures for reviewing compliance.

> *Although 20 CSR 2220-2.083 allows prescriptions to be maintained in an ERS in lieu of a hard copy, state/federal controlled substance laws still require that pharmacies maintain a hard copy of certain controlled substance prescriptions. [See chart in K.4]. Licensees are required to comply with federal law even if the prescription is maintained in an ERS.*

K.6 CONFIDENTIALITY

Patient records must be confidentially maintained in compliance with HIPAA and all state and federal law. The Board is aware that records may be reviewed by third-party entities conducting audit/review functions (e.g., pharmacy benefit managers, private consultants). Confidential records that do not relate to a third-party inquiry must be securely maintained to avoid unauthorized access/disclosure.

> *Pharmacies should exercise caution in discarding or destroying drug containers. Patient specific information should be removed before placing the container in the trash or giving the container to a reverse distributor.*

K.7 RECORD RETENTION

(This chart includes select record keeping requirements and is not a complete listing. Licensees should review all relevant laws to ensure record keeping compliance.)

PHARMACIST		
Continuing Education	*Must be retained for two (2) reporting periods immediately prior to renewal*	*20 CSR 2220-7.080*
PHARMACY		
Audit of Class-I Consultant Pharmacy Records	*3 Years*	*20 CSR 2220-2.010(10)(A)3.*
Class R Remote Dispensing Site Records Required by 20 CSR 2220-2.680	*2 Years*	*20 CSR 2220-2.680(7)*
Class Q Charitable Pharmacy Records required by 20 CSR 2220-2.685	*2 Years*	*20 CSR 2220-2.685(8)*
Compounding Log	*2 Years*	*20 CSR 2220-2.400(7)(E)*
Compounding Records	*2 Years*	*20 CSR 2220-2.400(7)(E)*
Controlled Substance Prescription Orders	*5 Years*	*§ 338.100, RSMo*
Controlled Substance Transfer Records/DEA 222 forms	*2 Years*	*21 CFR 1304.04*
Controlled Substance Inventories	*2 Years*	*§ 195.060, RSMo*
Distribution Records	*2 Years*	*20 CSR 2220-2.010(5)*
Drug Take-Back Records	*2 Years*	*20 CSR 2220-2.095(8)*
Drug Invoices	*2 Years*	*20 CSR 2220-2.010(5)*
Electronic Final Product Verification Records	*2 Years*	*20 CSR 2220-2.012(7)*
Immunization/Medication Administration Records	*2 Years*	*20 CSR 2220-6.050(6)(D)2.* *20 CSR 2220-6.040(6)(B)*
Immunization Protocol	*8 Years after termination*	*20 CSR 2220-6.050(5)(B)*
Medication Therapy Services (MTS) Protocol	*8 Years*	*20 CSR 2220-6.080(7)(B)*
MTS Patient Records (generally)	*7 Years*	*20 CSR 2220-6.080(7)*
Prescription Orders	*5 Years*	*§ 338.100, RSMo*
Remote Data Entry Activity Records	*5 Years*	*20 CSR 2220-2.725(3)(B)*

Remote Supervision Training/ Competency Assessment Records	*2 Years*	*20 CSR 2220-2.680(1)(C), (I); 20 CSR 2220-2.710(2)(C); 20 CSR 2220-2.725(3) (C); 20 CSR 2220-6.055(6)(B)*
Sterile Compounding Records	*2 Years*	*20 CSR 2220-2.200(9)(A)*
Technology Assisted Supervision Activity Records (Pharmacy Technicians & Intern Pharmacists)	*5 Years*	*20 CSR 2220-2.710(2)(D)*
Technology Assisted Verification (TAV) System Records	*2 Years*	*20 CSR 2220-2.012(7)*

L.1 AUTHORIZED ACTIVITY

Pharmacists, intern pharmacists, and qualified pharmacy technicians, who meet the following requirements may administer medication by prescription order: [§ 338.010, 20 CSR 2220-6.040]

	ADMINISTRATION REQUIREMENTS
Qualification Requirements	• Active Missouri RPh license • A Notification of Intent (NOI) filed with the Board (Notifications must be filed online). *Note: An administration NOI is different from an NOI to immunize by protocol. Both NOIs must be filed/renewed if a pharmacist will be doing both.* • Current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. The CPR/BLS program must include an in-person skill assessment. • Completion of a certificate program in medication administration and emergency procedures accredited by ACPE or an entity approved by the Board. The certificate program must include training in: a. Drug storage and handling b. Informed consent-requirements c. Pre- and post- administration assessment and counseling d. Biohazard waste disposal e. Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks. f. Administration techniques, including, hand-on training in routes of administration.**
Notification Renewal	NOIs must be refiled when your Missouri pharmacist license is renewed (every even-numbered year- 2024, 2026, etc.) To renew, pharmacists must have a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment. ****Proof of CPR/BLS certification from prior years should be maintained in the event of an audit (e.g., prior certification cards/ certificates)****
Missouri Licensed Intern Pharmacist	May administer if the intern: 1) Has a current and active CPR certification or qualifying BLS certification, and 2) Has completed a qualifying administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board [See 20 CSR 2220-6.040]. 3) Interns must be under the direct supervision of a pharmacist qualified to administer medicine.

Qualified Pharmacy Technician	Qualified pharmacy technicians may administer medication under the direct supervision of a qualified Missouri-licensed pharmacist if the pharmacy technician: 1) Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (NCCA), and*** 2) Has assisted in the practice of pharmacy as a registered or licensed pharmacy technician in Missouri or another U.S. state or territory for one (1) year, and 3) Has a current and active CPR certification or qualifying BLS certification, and 4) Has completed a qualifying medication administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board, and 5) Has an initial and, if applicable, annual documented assessment of competency in medication administration. [20 CSR 2220-6.040(2) (A)] A Missouri licensed pharmacist must be physically present on-site whenever a technician administers medication. See L.5 Authorized Delegation for additional requirements. **** Note: As of January 2023, the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA/ExCPT) are accredited by NCCA.*
Authorized Medication/Vaccines	As prescribed, however, licensees must comply with CDC recommendations or manufacturer guidelines.

*** If a requested route of administration was not included in the original certificate program, the pharmacist must first be trained in that administration route by a licensed heath care practitioner who is authorized to administer medication. No additional Board notification is required for the additional administration route. However, documentation of the training and training dates must be maintained at the pharmacy and available on request.*

L.2 PRESCRIPTION REQUIREMENTS

To administer medication, the prescription must contain:

1) The prescriber's name;
2) The patient's name;
3) The name of the drug and dose;
4) The route of administration;
5) The date of the original order; and
6) The date or schedule, if any, of each subsequent administration. [20 CSR 2220-6.040(5)]

Note: Prescriptions for administration by medical prescription order no longer have to include a statement that the drug is to be administered by a pharmacist. Prescriptions from non-Missouri prescribers have to comply with the law of the prescriber's state.

L.3 DRUG STORAGE

Drugs must be stored within the manufacturer's labeled requirements and appropriate temperature/humidity requirements (see E.5 Drug Storage). Vaccines must be stored in accordance with CDC guidelines. Storage requirements apply at all times, including, when administering outside of a pharmacy.

L.4 PATIENT EVALUATION

Patients must be asked to remain in the pharmacy for a "safe amount of time" after a vaccine is administered to observe any adverse reactions. [§ 338.010.12] "Safe amount of time" is not defined in statute. Pending further rulemaking, pharmacists should use their professional discretion when determining the time needed to adequately assess adverse reactions. The appropriate waiting period should be identified in the pharmacist's policies and procedures. The Board recommends documenting if a patient refuses or fails to stay as requested.

L.5 AUTHORIZED DELEGATION

Medication administration may be delegated to an intern pharmacist or qualified pharmacy technician who meets the training requirements in 20 CSR 2220-6.040(2) (see Training/Qualifications chart in L.1) Intern pharmacists and qualified pharmacy technicians do not have to file a Notification of Intent to administer medication, however, the supervising pharmacist and intern pharmacist/qualified pharmacy technician must maintain proof that the intern has met the required training, for a minimum of two (2) years. [20 CSR 2220-6.040(2)(B)]

DELEGATION TO OTHER HEALTHCARE PROVIDERS:

The Board has been asked if pharmacists can delegate medication administration to other non-pharmacy healthcare providers (e.g., a nurse, physician assistant, assistant physician). Pharmacies may use non-pharmacy healthcare providers to administer medication subject to the following:

1) The healthcare provider must have legal authority to administer the medication in question. Medication must be administered in compliance with the healthcare provider's authority, including, any patient screening requirements.
2) The pharmacy may use their pharmacy software system to conduct billing/reporting functions for medication administered by a non-pharmacy healthcare provider. If a prescription number is assigned to the billing/reporting record, the computer record and any hard copy or image should clearly indicate that it is a billing record and not a prescription record.
3) The pharmacy must be able to account for pharmacy medication inventory administered by the healthcare provider via billing or distribution records.
4) For healthcare provider-administered medication, any hard copy administration records should be physically separated from pharmacy administration records.
5) The administering healthcare provider does not have to be registered as a pharmacy technician, unless they will have independent access to drug inventory (e.g., without a pharmacist present and supervising).

Disclaimer: This procedure has not been reviewed for insurance billing and liability concerns. For legal advice, please consult an attorney. Healthcare providers should also contact their licensing Boards for their requirements.

L.6 POLICIES AND PROCEDURES

Pharmacists must have a current and accurate written policy and procedure manual that covers all aspects of administering medication by prescription order, including, but not limited to, policies/procedures for:

1) Drug administration
2) Authorized routes of administration
3) Drug storage
4) Pre- and post- administration assessment and counseling
5) Disposing of biohazard waste and used/contaminated supplies
6) Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions, and;
7) Recordkeeping and notification procedures/requirements.

L.7 RECORDS

The following records must be maintained for each administration:

1) The patient's name, address, and date of birth;
2) The date, route, and anatomic site of administration;
3) The medication's name and dose. For *vaccines* and *biologics*, the manufacturer, expiration date and lot number must also be recorded;
4) For vaccines, the name and address of the patient's primary health care provider ("PCP") as provided by the patient or an indication that PCP information was not given;
5) The nature of any adverse reaction and who was notified; and
6) The identity of the administering pharmacist. If medication was administered by an intern pharmacist or a qualified pharmacy technician, the identity of the supervising pharmacist and the intern pharmacist/qualified pharmacy technician. [20 CSR 2220-6.040(6)]

Administration records and the required policy and procedure manual must be maintained at the pharmacy where the prescription order is maintained separate from the pharmacy's prescription records for a minimum of two (2) years. If the medication was not administered on behalf of a pharmacy, required records may be maintained at a secure location designated by the pharmacist, provided the records must be produced within three (3) business days of a board request.

L.8 REPORTING/NOTIFICATIONS [20 CSR 2220-6.040(7)]

ADMINISTRATION BY PRESCRIPTION ORDER NOTIFICATION REQUIREMENTS

	WHEN?	NOTIFICATION REQUIREMENTS
Primary Care Provider (Vaccines Only)	****See L.9 Below****	****See L.9 Below****
Adverse Events	*Prescriber notification within twenty-four (24) hours after learning of an adverse event/reaction.*	*Prescriber notification is mandatory and cannot be waived.*
State/Federal Entities	*As required by law*	*As required by law*
ShowMeVax Reporting	****See L.9 Below****	****See L.9 Below****
Federal Vaccine Adverse Event Reporting System (VAERS)	*Within thirty (30) days of an adverse event or reaction*	*As provided by the U.S. Department of Health and Human Services. VAERS reports can be submitted via the federal online reporting system at: https://vaers.hhs.gov/reportevent.html*

Unless otherwise provided by federal law, required notifications may be made in writing, electronically, or via a common electronic record that is accessible to and shared by both the physician and pharmacist (e.g., a shared EMR/EHR). Documentation of the required notifications must be electronically retrievable on request or maintained at the pharmacy where the related prescription is maintained. Notification records maintained at a pharmacy must be separate from the pharmacy's prescription records.

Licensees must also comply with all state and federal laws governing Vaccine Information Statements and informed consent.

L.9 SHOWMEVAX REPORTING [§ 338.010.13]

Vaccines administered by medical prescription order must be reported to ShowMeVax- Missouri's statewide immunization registry- unless the patient opts out of reporting. [§ 338.010.13] If the patient opts-out of ShowMeVax reporting, the pharmacist must notify the primary care provider (PCP), if provided, within 14 days. *(See M.10 for ShowMeVax information and PCP notification requirements.)*

M.1 GENERAL REQUIREMENTS

Pharmacists who meet the qualifications in 20 CSR 2220-6.050 may administer the following vaccines pursuant to a written protocol with a Missouri licensed physician:

- Influenza
- Shingles
- Meningitis
- Pneumonia
- Hepatitis A/Hepatitis B
- Tetanus, diphtheria and pertussis (This includes combination products such as Tdap). [§ 338.010]

Licensees immunizing by protocol must comply with:

- All state and federal laws governing vaccine information statements and informed consent;
- Manufacturer guidelines, and;
- All applicable Centers for Disease Control (CDC) guidelines. In the event of a conflict between manufacturer guidelines and CDC guidelines, CDC guidelines control.

Unless otherwise restricted in the governing protocol, immunizations may be provided to patients that are seven (7) years or older or the CDC recommended age, whichever is higher. Immunizations may be delegated to an intern pharmacist who meets the requirements of 20 CSR 2220-6.050, or to a qualified pharmacy technician who meets the requirements of 20 CSR 2220-6.050 and 20 CSR 2220-6.055.

Pharmacists may immunize at any Missouri-licensed pharmacy, unless restricted by protocol. Pharmacists may also immunize at any non-pharmacy location if allowed by their protocol.

M.2 IMMUNIZATION QUALIFICATIONS [§ 338.010 and 20 CSR 2220-6.050]

Pharmacists, intern pharmacists, and qualified pharmacy technicians immunizing by protocol must meet the following requirements:

IMMUNIZATION BY PROTOCOL REQUIREMENTS	
Pharmacist Qualifications	• Active Missouri RPh license • Protocol with a Missouri licensed physician • Notification of Intent filed with Board (must be filed online prior to immunizing) • Current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. The CPR/BLS program must include an in-person skill assessment. • Completion of a certificate program in administering vaccines accredited by ACPE or an entity approved by the Board or provided by a regionally accredited pharmacy or medical school/college. The certificate program must include training in: 1. *Current CDC vaccine recommendations/guidelines for vaccines authorized by Chapter 338, including, immunization schedules* 2. *Basic immunology and vaccine protection* 3. *Pre- and post- vaccine screening or assessment* 4. *Physiology and techniques for administering vaccines, including, hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes and other common routes of vaccine administration* 5. *Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks.*
Pharmacist Notification Renewal	NOIs must be refiled when your Missouri pharmacist license is renewed (every even-numbered year- 2024, 2026, etc.) To renew, pharmacists must have: • A current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. • Two (2) CE hours (0.2 CEU) related to administering vaccines or CDC immunization guidelines. CE must be completed during the biennial renewal period (Nov. 1st to Oct. 31st of even numbered years) ****Proof of CPR/BLS certification from prior years should be maintained in the event of an audit (e.g., prior certification cards/ certificates)****

Missouri Licensed Intern Pharmacists	May immunize if the intern: 1) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment. 2) Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, & 3) Is working under the direct supervision of a pharmacist qualified to immunize
Qualified Pharmacy Technician	Pharmacists may delegate immunizations by protocol to a qualified pharmacy technician who is under the direct supervision of a qualified Missouri-licensed pharmacist if the pharmacy technician: 1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (NCCA), and** 2. Has assisted in the practice of pharmacy as a registered or licensed pharmacy technician in Missouri or another U.S. state or territory for one (1) year, and 3. Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment, and 4. Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, and 5. Has an initial and, if applicable, annual documented assessment of competency in medication administration. [20 CSR 2220-6.050(1) (D), (E)]. A Missouri licensed pharmacist must be physically present on-site and supervising when a qualified pharmacy technician is immunizing. See M.4 Immunization Delegation for additional requirements. ** Note: As of January 2023, the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA/ExCPT) are accredited by NCCA.

Section 338.010.12(3) requires that pharmacists post a certificate showing that he/she has met all immunization training requirements. The Board does not issue a separate immunization certificate/license. Instead, licensees should print and display their online license verification from the Board's website which will show if a Notification of Intent has been filed. Online license verifications can be retrieved by searching the licensee's name at https://pr.mo.gov/pharmacy-licensee-search.asp. Posting an immunization training

certificate does not meet the statutory requirement.

M.3 PROTOCOL REQUIREMENTS

To immunize, pharmacists must have a written protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(6)]. Protocols should clearly delineate the pharmacist's immunization authority. At a minimum, protocols must include:

1. The identity and signature of the participating pharmacist and physician;
2. The time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients who may be vaccinated;
5. Allowed routes and anatomic sites of administration;
6. Provisions for creating a prescription for each administration under the authorizing physician's name;
7. Emergency response procedures, including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. The length of time the pharmacist is required to observe a patient for adverse events;
9. Disposal procedures for used and contaminated supplies;
10. Authorization to administer vaccines at a non-pharmacy location;**
11. Record keeping and any notification requirements; and
12. Provisions for terminating the protocol at the request of any party at any time.

Protocol physicians no longer have to be within fifty (50) miles of the pharmacist. However, the protocol physician must be actively engaged in the practice of medicine.

Immunization protocols may be valid for no longer than one (1) year; a new protocol must be signed each year. Protocols must be maintained for at least eight (8) years after the protocol is terminated.

Protocol Amendments: Except as provided below, amendments to an immunization protocol must be manually or electronically signed and dated by all participating pharmacists and physicians. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. Protocol amendments must be signed and dated before they go into effect, and not retrospectively.

1. Additional Pharmacists: Pharmacists may be added to an existing protocol if the protocol is signed by both the newly added pharmacist and the authorizing physician(s). Existing pharmacists do not have to re-sign the protocol when a new pharmacist is added unless other protocol provisions are changed.
2. Changing/Adding Locations: Pharmacists may immunize by protocol at any Missouri-licensed pharmacy, unless otherwise restricted by the governing protocol. Authorization to immunize at a non-pharmacy location may be added to or removed from an existing protocol, if the physician signs and dates the protocol approving the change (a separate amendment document signed by the physician is acceptable). Existing pharmacists do not have to re-sign the protocol when non-pharmacy immunization authority is added/removed unless other protocol provisions are changed.

M.4 AUTHORIZED DELEGATION

Immunizations by protocol may be delegated to an intern pharmacist or qualified pharmacy technician who meets the rule's requirements. [20 CSR 2220-6.050(1)(D)]. Intern pharmacists and pharmacy technicians do not have to file a Notification of Intent to administer medication, however, the supervising pharmacist and

intern pharmacist/qualified pharmacy technician must maintain proof that the intern/qualified pharmacy technician has met the required training, for a minimum of two (2) years. [20 CSR 2220-6.050(1)(D)] (See M.2 chart for intern pharmacist/qualified pharmacy technician training requirements)

Qualified pharmacy technicians must be supervised by a Missouri-licensed pharmacist who is physically present on-site when vaccines are administered. [20 CSR 2220-6.050(8)]

DELEGATION TO OTHER HEALTHCARE PROVIDERS:

The Board has been asked if pharmacists can delegate their administration authority under 20 CSR 2220-6.050 to other non-pharmacy healthcare providers (e.g., a nurse, physician assistant, assistant physician). Pharmacies may use non-pharmacy healthcare providers to administer vaccines subject to the following:

1. The healthcare provider must have their own authority or their own protocol/standing order with a physician, in compliance with their regulatory agency's requirements, that gives them the authority to administer the vaccine.
2. The healthcare provider must administer the vaccine in compliance with their authority or protocol/standing order, including, any patient screening requirements.
3. The pharmacy may use their pharmacy software system to conduct billing/vaccine reporting for administrations provided by a healthcare provider. If a prescription number is assigned to the billing/reporting record, the computer record and any hard copy or image should clearly indicate that it is a billing record and not a prescription record.
4. The pharmacy must be able to account for pharmacy vaccine inventory administered by the healthcare provider via billing or distribution records.
5. For healthcare provider-administered vaccines, any hard copy vaccine administration record should be physically separated from pharmacy administration records.
6. The administering healthcare provider does not have to be registered as a pharmacy technician, unless they will have independent access to drug inventory (e.g., without a pharmacist present and supervising).

Disclaimer: This procedure has not been reviewed for insurance billing and liability concerns. For legal advice, please consult an attorney. Healthcare providers should also contact their licensing Boards for their requirements.

M.5 IMMUNIZATION LOCATIONS

Unless restricted by protocol, pharmacists who meet 20 CSR 2220-6.050's immunization requirements may immunize at any Missouri licensed pharmacy. For non-pharmacy locations, pharmacists may immunize off-site if authorized in their governing protocol. Effective April 28, 2021, immunization protocols only need to identify if pharmacists are allowed to immunize at a non-pharmacy location. Specific street addresses of non-pharmacy locations do not have to be listed in immunization protocols any longer (see 20 CSR 2220-6.050(1), (4)).

M.6 PATIENT EVALUATION

After immunizing, patients must be asked to remain in the pharmacy a "safe amount of time" to observe any adverse reactions. [§ 338.010.12(2)] The Board recommends defining the required waiting period in the governing protocol. In the absence of protocol language, pharmacists should use their professional

discretion to determine the time needed to adequately assess adverse reactions. The Board recommends documenting when a patient refuses to stay.

M.7 PRESCRIPTION REQUIREMENTS

Within seventy-two hours (72) hours after administering a vaccine by protocol, the pharmacist must either obtain a prescription from the authorizing physician for the vaccine or create a prescription under the protocol physician's name documenting the dispensing. [20 CSR 2220-6.050(7)(B)] . The protocol physician must be listed as the prescriber and not the pharmacist/intern pharmacist.

M.8 NOTIFICATIONS

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

	TIMEFRAME	NOTIFICATION REQUIREMENTS	NOTIFICATION METHOD
Authorizing Protocol Physician	*As required by protocol.*	*As required by protocol* ***Physicians may choose not to be notified.***	*As required by protocol.* ***Physicians may choose not to be notified.***
Primary Care Provider *(If different from the authorizing physician)*	*See M.10* *(ShowMeVax Reporting)*	*See M.10* *(ShowMeVax Reporting)*	*See M.10* *(ShowMeVax Reporting)*
Adverse Events	*Within twenty-four (24) hours after learning of a patient adverse event/ reaction*	*The authorizing physician and the patient's primary care provider must be notified, if different.*	*In the pharmacist's discretion unless defined in the protocol.*
Vaccine Adverse Event Reporting System (VAERS)	*Within thirty (30) days after learning of a patient adverse event/reaction*	*As provided by the U.S. Department of Health and Human Services*	*Online via the VAERS system*
ShowMeVax	*See Section M.10 below*	*See Section M.10 below*	*See Section M.10 below*

Unless otherwise required by state/federal law, required notifications can be made manually or electronically. Alternatively, notifications can be made through a common electronic medication record that is accessible to and shared by both the physician and pharmacist (e.g., a shared EMR/EHR). [20 CSR 2220-6.050(6)] Proof of the required notifications must be maintained in the pharmacist's records.

PCP notification is only required if the PCP's information is known. A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board suggests

documenting if the patient doesn't provide PCP information.

M.9 RECORDS

Pharmacists administering vaccines by protocol must document and maintain a record of:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist and, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician; and
6. Any adverse reaction and who was notified, if applicable.

Vaccination records must be maintained for at least two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not administered on behalf of a pharmacy, records should be maintained at an address identified in the protocol.

For additional immunization compliance information, see the Board's Immunization Checklist online at http://pr.mo. gov/boards/pharmacy/13863[1].pdf .

M.10 SHOWMEVAX REPORTING [§ 338.010.13]

Pharmacists are required to report all vaccines administered to ShowMeVax unless the patient opts out of reporting. [§ 338.010.13] ShowMeVax is Missouri's statewide immunization registry operated by the Missouri Department of Health and Senior Services (DHSS). The registry offers health care professionals, schools and child care organizations a single location for recording immunization history and status and allows providers to monitor vaccine inventory and upcoming required doses for patients. ShowMeVax reporting is required for vaccines administered by medical prescription order and vaccines administered by protocol.

Patients must be informed on a manual or electronic form that their information will be entered into the ShowMeVax system and provided an opportunity to opt-in to reporting. The patient must manually or electronically sign the form acknowledging that their information will be reported to ShowMeVax. A sample ShowMeVax Patient Notification Form is available on the Board's website. However, licensees should consult with legal counsel to develop the appropriate notification form for your practice setting. Notification forms should be maintained in the licensee's records as proof of compliance.

If the patient opts-out of ShowMeVax reporting, pharmacists must provide the following information to the PCP in writing within fourteen (14) days after immunizing:

1) The patient's name
2) The vaccine(s) administered
3) The administration route
4) The anatomic site of administration, and
5) The administration date.

Written notifications may be transmitted electronically or by fax/e-mail. Pharmacists must maintain documentation that the required notification was provided. PCP notification is not required if the patient doesn't provide PCP information.

Section 338.010.13 does not identify when vaccines have to be reported to ShowMeVax. Pending additional rulemaking, licensees should report to ShowMeVax within fourteen (14) days after immunizing.

Licensees are required to register with DHSS to report to ShowMeVax. Registration information is available on DHSS' website at https://health.mo.gov/showmevax/smv- providers.php. Registration is free.

Questions regarding ShowMeVax online reporting/registration should be directed to DHSS' Bureau of Immunizations at (877) 813-0933 or showmevaxsupport@health.mo.gov. The Board cannot answer ShowMeVax registration questions.

PCP notification is only required if the PCP's information is known. A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board suggests documenting if the patient doesn't provide PCP information.

N.1 GENERAL REQUIREMENTS

Pursuant to § 338.010, a Missouri licensed pharmacist may perform "medication therapy services" after obtaining a certificate of medication therapeutic plan authority from the Board. "Medication therapy services" are defined as:

> *[T]he designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. 20 CSR 2220-6.060(1)(F)*

Medication therapy services ("MTS") are different from medication therapy management ("MTM"). As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. MTM is within the scope of the practice of pharmacy and can be performed by any Missouri licensed pharmacist (e.g., Medicare Part D medication therapy management). A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy (e.g., Coumadin/Vancomycin dosing).

Modification of drug therapy includes, but is not limited to:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different, or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or generic substitution as authorized by § 338.056. Additionally, "medication therapy services" do not include administering medication by prescription order pursuant to 20 CSR 2220-6.040 or administering vaccines by protocol pursuant to 20 CSR 2220-6.050.

Prior to performing MT services, a pharmacist must have:

- A MTS certificate issued by the Board, and;
- A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri.

All pharmacists performing MT services in Missouri are required to have a MTS certificate issued by the Board, including, pharmacists practicing in a hospital. [§ 338.165.3]

N.2 CERTIFICATION REQUIREMENTS

To be issued a MTS certificate, pharmacists must submit an application to the Board with the applicable fee and:

1. Hold a PharmD degree from an ACPE accredited pharmacy school, or
2. Hold a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators, or
3. Have successfully completed a post-graduate MT certificate program accredited by ACPE, the American Society of Health-System Pharmacists, the American Society of Consultant Pharmacists, or

the American Pharmacists Association, or

4. Have completed a qualifying post-graduate MT certificate course that included instruction in:
    a. Assessing patient specific data and issues;
    b. Establishing MT goals or medication related action plans for identified medication conditions and medication related concerns;
    c. Assessing and addressing adverse reactions and adverse drug events;
    d. Modifying and monitoring medication regimens;
    e. Improving patient care and outcomes through MT services;
    f. Evaluating treatment progress;
    g. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
    h. Medication reconciliation;
    i. Drug utilization review;
    j. Applicable state or federal law;
    k. Formulating and documenting personal medication records;
    l. Documenting clinical outcomes;
    m. Interpreting, monitoring, ordering, and assessing patient test results; and
    n. Patient education and counseling.

N.3 SCOPE OF AUTHORITY

Licensees with a current MTS certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:

- Pharmacists may not initiate or modify any controlled substance.
- Pharmacists may not independently prescribe. Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- MT services may not be delegated. Pharmacy technicians and intern pharmacists may assist in providing MT services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.

N.4 PROTOCOL REQUIREMENTS

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist.

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist's scope of authority. As detailed in 20 CSR 2220-6.080(4), protocols must include:

1. The names and signatures of the participating physician(s) and pharmacists(s);
2. The effective date of the protocol;
3. A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the skill, education, training and competence of the authorizing physician and pharmacist;
4. A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case;
5. The specific drugs or drug categories included in the protocol;

6. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when providing MT services;
7. A description of any authority granted to the pharmacist to administer medication;
8. A list of drugs the pharmacist is authorized to administer;
9. A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform;
10. Procedures for documenting the pharmacist's MT decisions;
11. Procedures and requirements for communicating and reporting MT decisions to the authorizing physician;
12. Criteria for timely communication between the pharmacist and authorizing physician;
13. A statement prohibiting the pharmacist from delegating the responsibility of MT services;
14. Methods for physician review of MT activities;
15. Provisions allowing the authorizing physician to access patient records;
16. Mechanisms and procedures that allow the authorizing physician to override, rescind, or otherwise modify the protocol;
17. Emergency response procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;
18. All notification requirements required by 20 CSR 2220-6.080(5) (see N.9); and
19. An address where required records will be maintained.

Protocols must be signed and dated by both the authorizing physician and pharmacist. If a protocol includes multiple physicians and pharmacists, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol.

Alternatively, MT services may be provided pursuant to a protocol approved by the "medical staff committee" of a hospital or hospital system. A "medical staff committee" is defined as the "committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management" (e.g., Pharmacy & Therapeutics Committee). Protocols approved by a medical staff committee can only be used to provide MT services to "individuals receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility." A physician protocol is required for all other services.

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to being implemented. Protocols may be rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing.

Protocols must be reviewed and signed annually by the authorizing physician and pharmacist. The annual review date must be documented on the written protocol. Protocols do not have to be filed with the Board but must be available if requested. Additionally, both the pharmacist and authorizing physician must retain signed copies of the written protocol for eight (8) years after the protocol is terminated.

N.5 PHARMACY RESIDENTS

In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- The resident holds a MT certificate from the Board;

- The resident is enrolled in a residency training accredited by the American Society of Health System Pharmacists (ASHP) or that has a valid ASHP accreditation application pending, and;
- The resident is providing MT services under the supervision of a Missouri pharmacist with a current Board MT certificate.

N.6 PRESCRIPTION ORDERS

To provide MT services, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services for a specific patient. Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically, or in writing.

Pursuant to 20 CSR 2220-6.080(2)(A), the prescription order must include:

- The patient's name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (e.g., the patient's diagnosis or disease);
- The authorizing physician's name and address; and
- The length of time for providing MT services, if less than one (1) year.

Prescription orders maintained in compliance with 20 CSR 2220-6.080(2) will be deemed to comply with the general prescription requirements of 20 CSR 2220-2.018.

N.7 THERAPY MODIFICATIONS

Pharmacists with a MTS certificate may modify drug therapy or device usage as provided in the governing protocol. Pharmacists may only modify non-controlled medications; Controlled substances may not be modified by a pharmacist. [20 CSR 2220-6.080(6)(B)]. If the modification results in a drug/device being dispensed, the modification must be documented by creating a prescription in the pharmacy's prescription records under the name of the authorizing physician. [20 CSR 2220-6.080(6)(A)]. All therapy modifications must be documented in the patient's record.

Prescriptions generated by a pharmacist under 20 CSR 2220-6.080(6)(A) in the protocol physician's name may be dispensed by any licensed pharmacy. However, pharmacists may not sign their name or the physician's name to a written prescription generated under 20 CSR 2220-6.080(6). Instead, modifications may be verbally submitted to the other pharmacy or e-prescribed under the protocol physician's name in accordance with governing law and protocol.

N.8 DOCUMENTATION OF SERVICES

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. At a minimum, the patient record must include:

- The patient's name, birthdate, address and telephone number;
- The dates of any patient visits/consultations and the reason for the visit/consultation;
- Any pertinent assessments, observations or findings;
- Any diagnostic testing recommended or performed;
- The name of any medication or device modified;
- The strength, dose, dosage schedule or route of administration of any medication modified or administered;
- Referrals to the authorizing physician;

- Referrals for emergency care;
- Any contact with the authorizing physician concerning the patient's treatment or MT services plan;
- Any informed consent for procedures, medications or devices;
- Any changes/alterations made to the prescription order based on contact with the prescriber; and
- Any consultation with other treatment providers for the patient and the results of the consultation.

N.9 NOTIFICATIONS

Pharmacists must provide the following notifications [20 CSR 2220-6.080(5)]:

TYPE	RECIPIENT	TIMEFRAME
Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events	*Authorizing physician or physician's authorized designee*	*24 Hours*
Therapy modifications	*Authorizing physician or physician's authorized designee*	*24 Hours*
Other notifications	*As governed by protocol*	*As governed by protocol*

Notifications must be in writing unless otherwise authorized by protocol. Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law (e.g., an EMR). *Note: Protocols may include more stringent notification requirements.*

N.10 RECORDS

The following records must be maintained under 20 CSR 2220-6.080:

TYPE	TIMEFRAME
Patient records required by 20 CSR 2220-6.080(7)	*7 years after termination of protocol*
Protocols, including, protocol changes or amendments	*8 years after termination of protocol*
Prescription orders for MT services	*7 years after termination of protocol*
Other records required by protocol	*As governed by protocol*

Records may be maintained electronically provided the record can be retrieved/reviewed on request. Records maintained at a pharmacy must be produced during an inspection or investigation; Records not maintained at a pharmacy must be produced within three (3) business days.

N.11 RENEWAL/CONTINUING EDUCATION

MTS certificates must be renewed biennially with the pharmacist's Missouri pharmacist license. MTS certificate holders are required to complete 6 hours of CE in courses/programs related to medication therapy management each pharmacist biennial renewal period. The required CE may be used to satisfy Missouri's biennial pharmacist CE requirements.

The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Disease State Management/Drug Therapy ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).

O.1 REGISTRATION REQUIREMENTS

All pharmacy technicians must be registered with the Board. [§ 338.013, 20 CSR 2220-2.700]. A pharmacy technician is defined as:

- Any person who assumes a supportive role or who is utilized to "perform routine functions. . .in connection with the receiving, preparing, compounding, distributing or dispensing of medication", or
- Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis. [20 CSR 2220-2.700, 20 CSR 2220-2.090(2)(DD)]

Pursuant to the statutory/rule definitions, anyone involved in the handling of a filled prescription that is not ready for sale or delivery to the patient without further packaging, bagging, or manipulation must be registered as a technician, regardless of actual job title. Cashiers or delivery staff handling a filled prescription (patient vial/container, unit of use package, bubble card, etc.) that is that is not packaged/bagged for final sale or delivery to the patient are required to be registered as a technicians.

To be registered, an applicant must submit an application and undergo a criminal history background check. Applicants may begin working as a pharmacy technician once a completed registration application has been mailed to the Board. To be complete, the application must include an official fingerprint receipt and the required fee. A copy of the application must be maintained at the pharmacy. [§ 338.013]. The Board also suggests keeping proof of mailing.

Effective August 30, 2022, pharmacies no longer have to maintain a pharmacy technician list (see O.3 for current license posting and ID badge requirements).

PRACTICE TIPS:

- The pharmacist-in-charge is responsible for determining if an individual routinely has "independent access" to drug stock. Being able to access the pharmacy does not automatically require technician registration (e.g., an employee has a key to the pharmacy). However, individuals who routinely use their access to independently enter the pharmacy must be registered.
- Non-pharmacy staff may enter the pharmacy when a pharmacist is present to perform non-pharmacy functions without being registered as a pharmacy technician (e.g., cleaning/maintenance staff, auditors, IT staff, repairmen, HR representatives, corporate training staff). A pharmacist must be present when these individuals enter the pharmacy and must monitor/supervise visiting staff. Non-pharmacy staff members cannot assist with pharmacy practice unless properly registered as technicians. Proper security must be maintained in these instances; The Board has reviewed several cases where non-pharmacy staff diverted medication when visiting the pharmacy to perform routine functions, such as auditing, IT duties.
- *Job Shadowing/Mentoring Programs:* Unlicensed individuals may enter the pharmacy to observe as part of a job-shadowing or mentoring program, provided a pharmacist is present when these individuals enter the pharmacy to monitor/supervise visitors and the individuals do not assist in the practice of pharmacy in any manner. Proper security must be maintained and patient records must be secured to prevent visitors from accessing or viewing confidential patient information (e.g., paper, computer screens).

O.2 TECHNICIAN TRAINING/EDUCATION

Pharmacy technicians must be appropriately trained and competent to perform assigned duties [20 CSR 2220-2.010(1)(F)]. Missouri does not mandate certification or minimum education or training requirements to be registered as a technician. However, additional training is required for pharmacy technicians engaged in the following activities: (activities must be performed under pharmacist supervision):

ACTIVITY	REQUIRED TECHNICIAN TRAINING
Administering medication by prescription order [20 CSR 2220-6.040(2)(A)]	See O.6 for training requirements. **Pharmacy technicians do not have to file a Notification of Intent with the Board.*
Assisting a pharmacist with electronic final product verification	• Must be trained and competent to perform the duties assigned, and • Must have a documented initial and annual competency assessment using the pharmacy's approved electronic verification system.
Immunizing by protocol [20 CSR 2220-6.050(1)(E)]	See O.6 for training requirements. **Pharmacy technicians do not have to file a Notification of Intent with the Board.*
Sterile compounding under 20 CSR 2220-2.200	• Applicable sterile compounding didactic and experiential training; • Initial and ongoing aseptic skill assessment that includes media fill testing (See J.6 sterile compounding training requirements & media fill testing)
Technology Assisted Product Verification- Non-Controlled Medication Only [20 CSR 2220-2.012]	Must be competent to perform the duties assigned and must: 1. Hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies; 2. Have completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; 3. Have assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year; and 4. Have completed a documented initial and annual competency assessment. (See O.8)

Technicians preparing, compounding, repackaging, or dispensing radiopharmaceuticals or receiving/taking a radiopharmaceutical (nuclear) prescription drug order/ contingency prescription drug order (20 CSR 2220-2.500 Nuclear Pharmacies)	Must have successfully completed a nuclear pharmacy technician training program provided by an accredited college program, completed the American Pharmacist's Association's (APhA) Guidelines for Nuclear Pharmacy Technician Training Program or completed an equivalent company sponsored program that meets APhA's guidelines (see D.11)
Pharmacy technicians being remotely supervised at a Missouri licensed pharmacy under 20 CSR 2220-2.710 (non- dispensing activities only)	• Employer approved training in the activities performed and • A documented initial and annual competency assessment.
Pharmacy technicians operating at a remote data entry site under 20 CSR 2220-2.725	• Employer approved training in the activities performed and • A documented initial and annual competency assessment.
Pharmacy technicians being remotely supervised at a Class R Remote Dispensing Site pharmacy under 20 CSR 2220- 2.680	Pharmacy technicians must: 1. Hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies, and 2. Have completed employer approved training in the activities to be performed at the Class R pharmacy and have an initial and annual documented assessment of competency; and 3. Have assisted as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.
Authorized non-dispensing activities outside of a Missouri licensed pharmacy [20 CSR 2220-6.055(6)(B)]	• Employer approved training in the activities performed, and • A documented initial and annual competency assessment.

0.3 LICENSE POSTING/ID BADGES

Effective August 30, 2022, pharmacy technician registrations must either be posted in the pharmacy or maintained in a central location on the pharmacy's premises (e.g., on the pharmacy wall or in a binder or cabinet). A 2" x 2" photo must be attached to the technician registration. [20 CSR 2220-2.010(1)(L)] *Note: The photo requirement is new for technicians.* Technician registrations must be immediately retrievable during an inspection or available to the public if requested.

Pharmacy technicians working at more than one (1) pharmacy should maintain their license at the pharmacy that the technician considers to be their main or primary work location, and must have proof of licensure in their possession when assisting in the practice of pharmacy at any other pharmacy location (wallet card, current online verification from the Board's website).

All pharmacy technicians must wear an identification badge or a similar identifying article that identifies the technician's name and title when practicing or assisting in the practice of pharmacy. [20 CSR 2220-2.010(1)(L)1.] Pharmacies should establish policies/procedures regarding the types of allowed ID badges/articles and approved name format (full name, first name and last initial, first name only). Reusable and hand-written badges are acceptable as well as embroidered clothing/articles, if authorized by the pharmacy (e.g., smocks/jackets).

- Licensees have asked about using commonly known names, instead of the official name listed on the technician's registration. For example, licensees have asked if Anthony Michael Doe's ID badge can just read "Michael" if that is the name the licensee commonly uses. This is in the permit holder's discretion, however, the public and the Board should be able to easily identify staff if needed.
- The ID badge must include the licensee's/registrant's name and title. Abbreviations may be used if the public can easily identify the individual's license/registration title (e.g., technician, tech). Designations that the public may not be able to readily identify should not be used (e.g., CPhT). A patient should be able to easily distinguish when they are talking with a pharmacist and when they are talking with a pharmacy technician.

To ensure environmental quality, staff do not have to wear an ID badge/article while engaged in sterile compounding or in a controlled area as defined by 20 CSR 2220-2.200 (Sterile Compounding).

0.4 TECHNICIAN SUPERVISION

Pharmacy technicians must be properly supervised at all times to ensure delegated activities are properly performed in compliance with state/federal law. Supervision requirements will vary based on practice setting/activities; Technology assisted-supervision is authorized in some instances (see C.3). The supervising pharmacist remains responsible for delegated tasks, regardless of practice location or supervision method.

The information in this section applies to a Missouri-licensed pharmacy that is not a Class F (Renal Dialysis), Class L (Veterinarian), Class Q (Charitable), or Class R (Remote Dispensing Site) pharmacy. See the following rules/Practice Guide sections for supervision requirements applicable to these activities/pharmacy settings:

- Class F: Renal Dialysis Pharmacies (20 CSR 2220-2.600)
- Class L: Veterinary pharmacies (see D.13/20 CSR 2220-2.675)
- Class Q: Charitable Pharmacies (see D.15/20 CSR 2220-2.685)
- Class R: Remote Dispensing Sites (see D.16/20 CSR 2220-2.680)
- Remote data entry sites (see H.3, 20 CSR 2220-2.725), and
- Non-dispensing activities outside of a pharmacy (see C.5/20 CSR 2220-6.055)

Supervision At A Missouri-Licensed Pharmacy:

Except as otherwise authorized for Class F Renal Dialysis pharmacies, Class L Veterinary pharmacies, Class Q charitable pharmacies, and Class R Remote Dispensing Site pharmacies, pharmacy technicians assisting with pharmacy practice at a Missouri-licensed pharmacy must be under the direct supervision of a Missouri-licensed pharmacist who: (1) is "readily and immediately available" to render immediate assistance, and (2) able to identify or correct any errors before final dispensing. [§ 338.010.1; 20 CSR 2220-2.010(1)(B), 20 CSR

2220-2.710(1)]

"Readily and immediately available" means the supervising pharmacist must either be on the same physical premises as the pharmacy technician when supervising, or must supervise technician activities using technology that complies with 20 CSR 2220-2.710. The supervising pharmacist is responsible for ensuring full compliance with Missouri law, regardless of supervision method chosen (in-person or remote/technology-assisted). ***See C.3 for Technology Assisted Supervision Requirements***

Final prescriptions and the affixed labels must be verified by a pharmacist either personally or via an authorized electronic verification system (see H.4 and H.5). Effective August 28, 2022, rule 20 CSR 2220-2.012 allows a qualified pharmacy technician to verify non-controlled prescriptions/orders using a technology assisted verification system, if allowed by a Missouri licensed pharmacist (see O.7). A Missouri-licensed pharmacist must verify the accuracy of prescription/medication order data entered into an electronic prescription system by a pharmacy technician or intern pharmacist prior to dispensing for all prescriptions/medication orders. [20 CSR 2220-2.080(1)].

Pharmacy staff must terminate activities if a Missouri-licensed pharmacist is not supervising as required by 20 CSR 2220-2.010 and 20 CSR 2220-2.710 (in-person or via technology). To assist patients, the Board has determined technicians/intern pharmacists may accept written prescriptions at a pharmacy when a pharmacist is not supervising (in-person or via technology), but cannot take verbal prescription orders or otherwise assist with pharmacy practice.

"No Pharmacist On Duty Sign": A sign notifying the public that "no pharmacist is on duty" must be manually or electronically posted on the prescription counter and on all entrance doors if a pharmacist is not physically present at the pharmacy and personally supervising. [20 CSR 2220-2.010(1)(A)]. Sign lettering must be at least two (2) inches in height. The "no pharmacist on duty" sign is required even if the pharmacy is being remotely supervised using technology.

> *The Board has determined the "no pharmacist on duty" sign does not have to be posted if the pharmacist is briefly absent from the pharmacy area (e.g., a restroom break).*

(See C.2 and C.3 for additional supervision information and examples)

0.5 REMOTE/TECHNOLOGY ASSISTED-SUPERVISION

A Missouri-licensed pharmacist may use technology to remotely supervise pharmacy technicians:

- Assisting at a Missouri at a licensed pharmacy, provided the technician is not compounding, preparing or dispensing medication (see C.2, O.4)
- Assisting at a Class R Remote dispensing pharmacy (see D.16)
- Assisting at a remote data entry site (see H.3), or
- Assisting with non-dispensing activities at a non-pharmacy site as authorized by 20 CSR 2220-6.055 (*see C.5*)

Required technology and remote supervision allowances/restrictions will vary based on the specific practice setting. Additional technician training requirements also apply. Licensees should review the above sections for additional compliance information.

Summary of Allowed Remote/Technology-Assisted Supervision

(Licensees should review the rules and applicable Practice Guide sections for all compliance requirements; Additional restrictions/requirements apply that are not listed below.)

	TECHNICIAN ASSISTING AT A MISSOURI LICENSED PHARMACY (20 CSR 2220-2.710) *TECH IS ON-SITE & RPH IS OFF-SITE/ NOT AVAILABLE	REMOTE DATA ENTRY SITE (20 CSR 2220-2.725)	OFF-SITE NON-DISPENSING ACTIVITIES (20 CSR 2220-6.055)	CLASS R REMOTE DISPENSING PHARMACY SITES (§ 338.215)
Technology assisted supervision?	✓ ***Technology must allow the supervising pharmacist to communicate with staff and monitor staff activities. Remote/technology assisted supervision not allowed for technicians/ Intern pharmacists compounding, preparing or dispensing medication*	**Recommended but not required*	✓ **Technology must allow the supervising pharmacist to communicate with staff and monitor staff activities*	✓ **Technology must allow the supervising pharmacist to communicate with staff and monitor staff activities*
Real-time audio communication mechanism between pharmacist & technician/intern pharmacist?	** "Sufficient" communication method required; Real-time communication method recommended but not required*	✓	✓	✓
Video technology?	** If needed to verify and ensure activities*	** If needed to verify and ensure activities*	** If needed to verify and ensure activities*	✓

	are safely and properly performed.	*are safely and properly performed.*	*are safely and properly performed.*	
Completion of employer training?	✓	✓	✓	✓
Initial & annual competency assessment?	✓	✓	✓	✓
Pharmacy technician certification?	X	X	X	✓ **Certification required for technicians being remotely supervised*

0.6 AUTHORIZED ACTIVITIES

Technicians may not perform any activity that requires the "professional judgment" of a pharmacist. [20 CSR 2220- 2.700(1)]. Prohibited activities include, but are not limited to:

- Final verification of a prescription before dispensing, except as otherwise authorized by 20 CSR 2220-2.012 for technology assisted final product verification;
- Drug utilization review;
- Patient counseling (prescription or OTC);
- Receiving or providing transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)]; and
- Modifying medication therapy [20 CSR 2220-6.080]

TECHNICIAN AUTHORIZED DUTIES ***The chart below is not exhaustive and does not include all potential tasks that may be performed by a pharmacy technician. All authorized activities must be performed under the direct supervision of a Missouri licensed pharmacist. X= Activities not allowed***.	
Administer Medication by Rx Order	✓ (See O.7 for additional information/requirements)
Advise/Counsel Patients on OTC Items	X
Fill, Compound or Prepare a Prescription	✓
Dispense Rx to Patient	✓
Drug Utilization Review	X
Enter Rx Data	✓
Immunize by Protocol	✓ (See O.7 for additional information/requirements)
Modify Medication Therapy under MTS protocol	X
Offer Patient Counseling	✓
Patient Counseling	X
Receive Rx	✓
Receive or provide controlled substance transfer information	X
Request refill authorization	✓
Verify Final Product	See O.8 for allowed technology assisted product verification for non-controlled medication.

***See P.4 chart for authorized pharmacy technician vs. intern pharmacist duties.*

*****IMPORTANT NOTE ON PATIENT COUNSELING*****

OBRA-90 and Board rule 20 CSR 2220-2.190 require that patients must be offered an opportunity to consult with a pharmacist each time a new or refill prescription is dispensed (see D.16 for mandatory patient counseling for Class R Remote Dispensing Sites). Once requested, patient counseling may only be conducted by a pharmacist or an intern pharmacist operating under the pharmacist's direct supervision. Technicians cannot provide patient counseling under any circumstances.

Inspectors have observed multiple instances of technicians intentionally or inadvertently providing patient counseling. Examples include:

- Technicians answering questions about a medication's indication directly or pharmacists telling a technician what to say in response to a counseling request
- Technicians recommending over-the-counter (OTC) products to treat a specific issue
- Technicians explaining medication storage and administration directions (even when the information is being read from the prescription label or auxiliary labels), and
- Technicians informing patients of side effects they may experience after being vaccinated or taking

prescription/OTC medication.

These activities constitute patient counseling and cannot be performed by a technician. Talk with pharmacy staff to make sure they understand what constitutes patient counseling and what technicians are allowed to do.

Patient counseling is one of the most important clinical services a pharmacist can provide and can help identify dispensing errors. Make sure your technicians are compliant with the law and are not counseling patients, either directly or indirectly.

0.7 IMMUNIZING/ADMINISTERING MEDICATION

Administering Medication by Prescription Order:

20 CSR 2220-6.040 allows pharmacists to delegate administration by medical prescription to a "qualified pharmacy technician" who:

- Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (NCCA), and***
- Has assisted in the practice of pharmacy as a registered or licensed pharmacy technician in Missouri or another, or another U.S. state or territory for one (1) year, and
- Has a current and active CPR certification or qualifying BLS certification, and
- Completes a qualifying medication administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board, and
- Has an initial and, if applicable, annual documented assessment of competency in medication administration [20 CSR 2220-6.040(2)(A)]

**** Note: As of January 2023, the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA/ExCPT) are accredited by NCCA.*

Pharmacy technicians must be supervised by a Missouri-licensed pharmacist who is physically present on-site when medication is being administered. [20 CSR 2220-6.040(9)]. Pharmacy technicians do not have to file a Notification of Intent with the Board to administer medication, however, the supervising pharmacist must maintain proof that the pharmacy technician has met the required training, for a minimum of two (2) years.

Immunizing by Protocol

20 CSR 2220-6.050 allows pharmacists to also delegate immunizations by protocol to a "qualified pharmacy technician" who:

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (NCCA), and***
2. Has an initial and annual documented competency assessment in vaccine administration; and
3. Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment, and
4. Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, and
5. Has assisted in the practice of pharmacy as a registered or licensed pharmacy technician in a U.S. state or territory for one (1) year. [20 CSR 2220-6.050(1)(E)]. *Note: The required one (1) year practice experience can be earned in a Missouri or in another U.S. state/territory.*

*** Note: As of January 2023, the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA/ExCPT) are accredited by NCCA.*

See the Board's website for a Technician/Intern Pharmacist Immunization Assessment Template

Pharmacy technicians must be supervised by a Missouri-licensed pharmacist who is physically present on-site when vaccines are administered. [20 CSR 2220-6.050(8)] Pharmacy technicians do not have to file a Notification of Intent with the Board to immunize, however, the supervising pharmacist must maintain proof that the pharmacy technician has met the required training for a minimum of two (2) years. [20 CSR 2220-6.050(1)(E)]

0.8 TECHNOLOGY ASSISTED PRODUCT VERIFICATION

Effective August 30, 2022, a Missouri licensed pharmacist may allow an "authorized pharmacy technician" or "authorized intern pharmacist" to verify a final prescription/ medication order for a non-controlled substance using a technology assisted verification system (TAVS), in lieu of final product verification by a pharmacist. [20 CSR 2220-2.012.] A TAVS is defined as:

> *An electronic system that utilizes barcode technology or another electronic process/method to electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient.* [20 CSR 2220-2.012(1)(D)]

An "authorized pharmacy technician" is defined as a currently registered Missouri pharmacy technician who:

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;
2. Has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; and
3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year. [20 CSR 2220-2.012(1)(B)]

See H.6 (Technology Assisted Verification) for a full list of TAVS requirements and restrictions. *Note: Qualified technicians using a TAVS must be under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance whenever medication is being prepared/dispensed or verified using a TAVS. [20 CSR 2220-2.010(1)]*

0.9 NAME, ADDRESS & EMPLOYMENT CHANGES

- Name Changes: Name changes must be submitted to the Board in writing along with legal documentation of the change (e.g., marriage certificate, court order, divorce order). Once received, the current name will be officially changed in the Board records. A Duplicate License Request application must be submitted to have a new registration printed and mailed reflecting the new name (applications are online; fees will apply).
- Address & Employment Changes: Address and employment changes must be submitted to the Board no later than fifteen (15) days after the change. [20 CSR 2220-2.010(1)(N); 20 CSR 2220-2.700(3)]. Changes can be submitted online at https://pr.mo.gov/pharmacists-coa.asp.

0.10 RENEWALS

Technician registrations are valid for one (1) year and expire annually on May 31st. A technician may not work if his/her registration is not renewed by May 31st. [§ 338.013.5]. Technicians who fail to renew by May 31st may submit a late renewal application until June 30th. Although the Board will accept the renewal application, the individual cannot work after May 31st until his/her registration has been renewed by the Board. Applicants wishing to renew after June 30th will be required to submit a new technician registration application and undergo a new criminal history background check.

Registration status may be checked on the Board's website at https://pr.mo.gov/pharmacy-licensee-search.asp. Practicing without a valid registration and/or allowing unlicensed practice constitutes grounds for discipline. [§ 338.055.2(10)].

0.11 MANDATORY REPORTING OF TECHNICIAN DISCIPLINE [§ 338.013.10]

Pharmacies and hospitals are required to report to the Board any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055. This requirement applies to any form of final disciplinary action, including, but not limited to, termination, probation, suspension, demotion, or reassignment.

Pharmacies and hospitals must also report any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055. *(See E.17 Reporting of Discipline/Adverse Actions.)*

Notification of Technician Action must be filed with the Board electronically or in writing within fifteen (15) days after the action and must include:

- The name and permit number of the pharmacy;
- The name and contact information for the person making the notification;
- The technician's name and registration number;
- Date of action; and
- Reason for action. [20 CSR 2220-2.010(4)]

Notification of Technician Action notices may be filed electronically on the Board's website.

0.12 DISCIPLINED/DISQUALIFIED TECHNICIANS

The Board is statutorily authorized to take the following licensure/disciplinary action against pharmacy technicians:

TYPE OF ACTION	DESCRIPTION	AUTHORIZED TO WORK
Employment Disqualification	*Technicians/Applicants disciplined or denied registration for cause under § 338.055, RSMo*	*NO*
Conditional Registration	*Technicians/Applicants disciplined under § 338.055, RSMo but allowed to continue*	*Yes, subject to restrictions printed on the back of the printed registration.*

	working	
HB 600 (Tax Suspension)	*Technicians suspended by the Missouri Department of Revenue by operation of law for failure to file a tax return or delinquent state taxes.*	*NO*

The Employment Disqualification List, Conditional Registration List and HB 600(Tax) List are available on the Board's website. These lists are updated frequently. Register for the Board's e-alerts to receive free electronic updates when individuals are added to the lists.

Licensees are responsible for ensuring technicians are appropriately authorized to work. The Board recommends designating a specific person and setting regular intervals for checking the Board's listings.

In addition to Board actions, the federal Department of Health and Human Service, Office of the Inspector General Exclusion List (OIG List) includes entities/persons excluded from participating in Medicare, Medicaid and other federal health care programs. Employers participating in qualified federal programs are generally prohibited from employing individuals on the OIG list. For additional information, visit OIG's website at https://oig.hhs.gov/exclusions/index.asp. *Note: OIG exclusions/waivers also apply to pharmacists and interns.* MoHealthNet also maintains a list of providers that have been terminated from participating in the MoHealthNet program that is available online at: https:// mmac.mo.gov/providers/provider-sanctions/

REQUIRED STATE/FEDERAL WAIVERS

WAIVERS: Both state and federal law prohibit an employer from hiring individuals with certain controlled substance related convictions without an employment waiver [see 21 CFR 1301.76(a); 19 CSR 30-1.034]. Specifically, employers are required to obtain a DEA waiver for felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration.

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA.

0.13 TECHNICIAN COMPLIANCE RESOURCES

The Board has published a Pharmacy Technician Guide that includes specific compliance information for Missouri technicians. The Board has also published an online Technician Quiz that can be used to test staff's knowledge of Missouri's technician requirements. The free online quiz can be taken anonymously and can help assess a technician's understanding of Missouri law. Recordings of webinars on technician issues may be found http://pr.mo.gov/pharmacists- publications-resources.asp#videos.

P.1 LICENSE REQUIREMENTS

All intern pharmacists must hold an active Missouri intern pharmacist license issued by the Board. To be eligible for licensure, applicants must be enrolled in an ACPE school/college of pharmacy or be actively seeking to earn additional pharmacy practice hours to qualify for a Missouri pharmacist license. Applicants who are no longer enrolled in school or who have completed the qualifying practice hours/experience requirements are not eligible for a Missouri intern pharmacist license.

Although not required for licensure, the following additional training is required for intern pharmacists engaged in the activities below (*activities must be performed under pharmacist supervision*):

ACTIVITY	REQUIRED TRAINING
Administering medication by prescription order under 20 CSR 2220-6.040	Intern pharmacists must: • Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, the American Red Cross, or an equivalent organization; • Have successfully completed a certificate program in medication administration, and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy (see 20 CSR 2220-6.050 for additional course requirements), and; • Training in any routes of administration not included in the intern pharmacist's qualifying certificate program. Training must be completed prior to administration via the applicable route. **Intern pharmacists do not have to file a Notification of Intent with the Board.*
Assisting at a Class Q Charitable Pharmacy without a pharmacist present	• Employer approved training in the activities performed and • An initial and annual documented competency assessment
Assisting a pharmacist with electronic final product verification under 20 CSR 2220-2.011 (Must be supervised by a pharmacist)	• An initial and annual documented competency assessment using the pharmacy's approved electronic final product verification system

Immunizing by protocol under 20 CSR 2220-2.650	Intern pharmacists must: • Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, the American Red Cross, or an equivalent organization; and • Have completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy (see 20 CSR 2220-6.040 for additional course requirements). **Intern pharmacists do not have to file a Notification of Intent with the Board.*
Sterile compounding under 20 CSR 2220-2.200	• Applicable sterile compounding didactic and experiential training, and • Initial and ongoing aseptic skill assessment that includes media fill testing (See J.6 sterile compounding training requirements & media fill testing)
Technology Assisted Prescription/Medication Order Verification *(Must be supervised by a pharmacist)*	• Employer approved training in technology assisted verification using the pharmacy's approved technology assisted verification system • An initial and annual documented competency assessment
Intern pharmacists being remotely supervised at a Missouri licensed pharmacy under 20 CSR 2220-2.710 (non- dispensing activities only)	• Employer approved training in the activities performed and • An initial and annual documented competency assessment
Intern pharmacists operating at a remote data entry site under 20 CSR 2220-2.725	• Employer approved training in the activities performed and • An initial and annual documented competency assessment.
Intern pharmacists being remotely supervised at a Class R Remote Dispensing Site pharmacy under 20 CSR 2220- 2.680	• Employer approved training in the activities performed and • An initial and annual documented competency assessment.
Non-dispensing activities outside of a Missouri licensed pharmacy [20 CSR 2220-6.055(6)(B)]	• Employer approved training in the activities performed, and • An initial and annual documented competency assessment.

Intern pharmacist licenses must be renewed by December 31st of every even numbered year (e.g., 2022, 2024, 2026). Renewal information is mailed around October 1st of each renewal year. Intern pharmacists may not continue to practice or earn experiential hours if their license is not renewed and active.

Missouri requires 1,500 pharmacy practice experience hours to obtain a Missouri pharmacist license. The Board will only recognize or certify hours earned as a licensed intern pharmacist. Hours earned as a pharmacy technician cannot be used to satisfy the required intern pharmacy practice experience hours.

**An Intern Pharmacist Guide is available on the Board's website for students enrolled at St. Louis College of Pharmacy (STLCoP) and UMKC School of Pharmacy. A separate Intern Pharmacist Guide is available online for students not enrolled in or graduated from UMKC or STLCoP. Intern pharmacists/preceptors should review the brochures to ensure compliance with Missouri law.*

P.2 LICENSE POSTING/ID BADGES

Effective August 30, 2022, intern pharmacist licenses must either be posted in the pharmacy or maintained in a central location on the pharmacy's premises (e.g., on the pharmacy wall or in a binder or cabinet). A 2" x 2" photo must be attached to the actual license. [20 CSR 2220-2.010(1)(L)] *Note: The photo requirement is new for intern pharmacists.* Individual licenses must be immediately retrievable during an inspection or available to the public if requested.

Intern pharmacists working/earning hours at more than one (1) pharmacy should maintain their license at the pharmacy that the intern pharmacist considers to be their main or primary location, and must have proof of licensure in their possession when assisting in the practice of pharmacy at any other pharmacy location (wallet card, current online verification from the Board's website).

Intern pharmacists must wear an identification badge or a similar identifying article that identifies the intern pharmacist's name and title when practicing or assisting in the practice of pharmacy. [20 CSR 2220-2.010(1)(L)1.] Pharmacies should establish policies/procedures regarding the types of allowed ID badges/articles and approved name format (full name, first name and last initial, first name only). Reusable and hand-written badges are acceptable as well as embroidered clothing/articles, if authorized by the pharmacy (e.g., smocks/jackets).

- Licensees have asked about using commonly known names, instead of the official name listed on the Board's license. For example, licensees have asked if Anthony Michael Doe's ID badge can just read "Michael" if that is the name the licensee commonly uses. This is in the permit holder's discretion, however, the public and the Board should be able to easily identify staff if needed.
- The ID badge must include the licensee's/registrant's name and title. Abbreviations may be used if the public can easily identify the individual's license title (e.g., intern pharmacist, intern. Pending further guidance from the Board, "student" or "student pharmacist" may also be used for interns.

> * *To ensure environmental quality, staff do not have to wear an ID badge/article while engaged in sterile compounding or in a controlled area as defined by 20 CSR 2220-2.200 (Sterile Compounding).*

P.3 INTERN SUPERVISION

Intern pharmacists must be properly supervised at all times to ensure delegated activities are properly performed in compliance with state/federal law. Intern pharmacists are learning how to practice pharmacy, and are not just additional pharmacy help. Sufficient supervision, training, and instruction should be provided to help ensure intern pharmacists are competent to practice in the future.

Intern pharmacist supervision requirements will vary based on practice setting/activities; Technology assisted- supervision is authorized in some instances. The supervising pharmacist remains responsible for delegated tasks, regardless of practice location or supervision method. The following Board rules address intern pharmacist supervision in the practice settings/activities identified below:

- 20 CSR 2220-2.710: Supervision requirements for all practice settings/Technology Assisted Supervision (See C.2, C.3)
- 20 CSR 2220-2.725: Remote data entry sites (See H.3)
- 20 CSR 2220-2.600: Class F Renal Dialysis Pharmacies (See D.2)
- 20 CSR 2220-2.675: Class L Veterinary pharmacies (See D.13)
- 20 CSR 2220-2.685: Class Q Charitable Pharmacies (See D.15)
- 20 CSR 2220-2.680: Class R Remote Dispensing Sites (See D.16).
- 20 CSR 2220-6.055: Non-dispensing activities outside of a pharmacy (See C.5)

Licensees should review the above rules and Practice Guide sections for compliance requirements applicable to each setting/activity.

P.4 AUTHORIZED ACTIVITIES

Intern pharmacists must be trained and competent to perform assigned duties. [20 CSR 2220-2.010(1)(F)] Except as otherwise provided below, intern pharmacists may assist a pharmacist in any area of pharmacy practice while under pharmacist supervision, including:

- Preparing, compounding or dispensing medication
- Patient counseling (except for remote patient counseling at a Class R Remote Dispensing Site; See D.16)
- Administering medication by prescription order (see P.7)**
- Immunizing by protocol (see P.7) **
- Assisting with medication therapy services, provided intern pharmacists may not modify therapy (See Section N), and**
- Technology assisted product verification for non-controlled medication (see H.6)**

***Additional intern training requirements apply.*

Intern pharmacists may not:

- Modify medication therapy (see Section M)
- Remotely supervise a Class R Remote Dispensing Pharmacy site
- Independently supervise pharmacy technicians (in-person or via technology)
- Provide remote patient counseling for a Class R pharmacy (see D.16), or
- Receive or provide transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)]

INTERN VS. PHARMACIST TECHNICIAN AUTHORIZED DUTIES ***This chart below is not exhaustive and does not include all potential tasks that may be performed by a pharmacy technician/intern pharmacist. All authorized activities must be performed under the direct supervision of a Missouri licensed pharmacist. X= Activities not allowed***.		
	INTERN PHARMACIST*	PHARMACIST TECHNICIAN*
Administer Medication by Rx Order	✓ **If under the direct supervision of a pharmacist authorized to administer medication by protocol; Additional training requirements apply.*	✓ **If under the direct supervision of a pharmacist authorized to administer medication. The supervising pharmacist must be physically present on-site and supervising when a technician administers medication. Additional technician training is also required.*
Advise/Counsel Patients on OTC Items	✓	X
Dispense Rx to Patient	✓	✓
Drug Utilization Review	✓	X
Electronic Final Product Verification	X	X
Enter Rx Data	✓	✓
Immunize by Protocol	✓ **If under the direct supervision of a pharmacist authorized to administer medication by protocol; Additional training requirements apply*	✓ **The supervising pharmacist must be physically present on-site and supervising when a technician administers medication. Additional technician training is also required.*
Modify Medication Therapy under MTS protocol	X	X
Patient Counseling (excluding remote patient counseling for a Class R pharmacy)	✓	X
Prepare/Compound Rx	✓	✓
Receive Rx	✓	✓

Receive or provide controlled substance transfer information	X	X
Request refill authorization	✓	✓
Verify Final Product	**Technology assisted final product verification allowed for non-controlled medication only under 20 CSR 2220-2.012 (see H.6) Additional training requirements apply and must be under the direct supervision of a pharmacist who is physically present in the dispensing area.*	**Technology assisted final product verification allowed for non-controlled medication only under 20 CSR 2220-2.012 (see H.6) Additional training requirements apply and must be under the direct supervision of a pharmacist who is physically present in the dispensing area.*

P.5 IMMUNIZING/ADMINISTERING MEDICATION

Intern pharmacists may administer medication by medical prescription order if the intern pharmacist:

1) Is working under the direct supervision of a pharmacist who is also qualified to administer medication by medical prescription order under 20 CSR 2220-6.040,
2) Completes a qualifying administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board [See 20 CSR 2220-6.040]; and
3) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment.

Similarly, an intern pharmacist may immunize by protocol if the intern pharmacist:

1) Is working under the direct supervision of a pharmacist qualified to immunize under 20 CSR 2220-6.050,
2) Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program [See 20 CSR 2220-6.050], and
3) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment.

Intern pharmacists do not have to file a Notification of Intent with the Board to administer medication by medical prescription order or to immunize by protocol.

P.6 TECHNOLOGY ASSISTED PRODUCT VERIFICATION

Effective August 30, 2022, a Missouri licensed pharmacist may allow an "authorized intern pharmacist" to verify a final prescription/ medication order for a non-controlled substance using a technology assisted verification system (TAVS), in lieu of final product verification by a pharmacist. [20 CSR 2220-2.012.] A TAVS is defined as:

> *An electronic system that utilizes barcode technology or another electronic process/method to*

electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient. [20 CSR 2220-2.012(1)(D)]

An "authorized intern pharmacist" is defined as an individual who holds a current and active Missouri intern pharmacist license and has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system.

See H.6 for a detailed list of intern pharmacist TAVS requirements and restrictions. Intern pharmacists must be under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and who is able to provide immediate assistance whenever medication is being prepared/dispensed or verified using a TAVS.

P.7 INTERN SITE/PRECEPTOR APPROVAL

The Board has published an Intern Pharmacist Guide for students enrolled at St. Louis College of Pharmacy (STLCoP) and the UMKC School of Pharmacy and a separate Intern Pharmacist Guide for students/intern pharmacists not enrolled in or graduated from UMKC or STLCoP. The Intern Pharmacist Guides are available online and contain detailed information on earning experiential hours and intern site/preceptor approval and reporting requirements. Students earning experiential hours as part of the curriculum of an ACPE accredited pharmacy school/college should contact the applicable school for information on site and preceptor approvals and preceptor reporting of intern hours. (See the Intern Guide and 20 CSR 2220 Chapter 7 for exemptions/requirements).

For intern pharmacists earning hours outside of their pharmacy school/college curriculum (e.g. a summer job), an Intern Site and Preceptor Application is required if the intern pharmacist wants the Missouri Board of Pharmacy to certify the practice hours earned. Intern pharmacists may begin earning hours after Board approval of the site/preceptor. A Preceptor's Affidavit of Intern Hours must be submitted to the Board in order for the Board to certify the hours. The Preceptor's Affidavit must be signed by both the preceptor and intern pharmacist (the preceptor's signature must be notarized). The office recommends submitting hours quarterly or immediately after the internship/training period ends. The Board will not certify or recognize hours that are not reported to the Board.

Q.1 LICENSE REQUIREMENTS

A Missouri Class-C Long-Term Care pharmacy permit is required if a pharmacy provides prescription services to a long-term care ("LTC") facility or dispenses legend drugs/devices to patients residing in a LTC facility. [20 CSR 2220-2.140]. A Class C permit is required regardless of the number of patients served (e.g., one patient or the entire facility) or the packaging used for the LTC patient (e.g., dispensing a bottle vs. a bubble pack). As used in the Board's rules, a "long-term care facility" is defined as a "nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients." [20 CSR 2220-2.020(9)(C)].

Pursuant to 20 CSR 2220-2.140(2), Class C pharmacies must have a policy and procedure manual that includes:

- Methods for timely dispensing medication;
- Procedures for notifying the facility when a medication is not readily available;
- Labeling requirements and policies;
- Policies/procedures for appropriate medication destruction and/or returning unused medication, as authorized by state and federal law; and
- Policies/procedures for securing, delivering, storing and handling emergency kits.

Q.2 AUTHORIZED DISPENSING

Licensees may dispense legend drugs to a LTC resident upon receipt of a prescription or a "prescription drug order." For purposes of LTC dispensing, a "prescription drug order" is defined as "an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device." [20 CSR 2220-2.140(5)]. Generic substitution is authorized unless otherwise restricted by the prescriber (see H.11).

Pharmacies may maintain a separate file for LTC prescription drug orders, provided that a separate numbering system is used. [20 CSR 2220-2.140(5)(C)]. Pharmacies using interim dispensing/partial fill systems must have records that clearly record these dispensings as any other new or refill dispensing. Pharmacies using an electronic record keeping system must document interim dispensings/partial fills in the electronic system and may not record them in a manual record system.

Refills/Transfers: Nursing home orders are not transferable if the patient is discharged from the facility. Additionally, refills associated with a nursing home order are not valid for use outside of the facility. [20 CSR 2220-2.140(5)(D)]. For prescriptions/medication orders, 20 CSR 2220-2.120(4) allows Class-C pharmacies to transfer up to a seventy-two (72) hour supply of a non-controlled prescription/medication order to a second pharmacy for initial dispensing without voiding the remaining prescription. The amount transferred must be deducted from the remaining prescription/medication order but the prescription at the transferring pharmacy no longer has to be voided. A Class J Shared Services permit is not required for pharmacies that have an arrangement to provide only initial dispensing services for a Class C pharmacy, as allowed under 20 CSR 2220-2.120(4) and20 CSR 2220-2.650(4).

Q.3 PREPARATION/PACKAGING

Personnel packaging drugs must wear gloves when handling individual tablets and capsules [20 CSR 2220-2.010(1)(I)]. Drug containers must meet USP minimum requirements, including, but not limited to, single

unit, unit dose, and unit-of-use containers. [20 CSR 2220-2.140(2)(C)]. If applicable, light sensitive packaging must be used. Internal liners must always be replaced before refilling the container. If drugs are dispensed in a container other than the manufacturer's original container, the container must bear the manufacturer's expiration date or a twelve (12) month expiration date, whichever is less. [20 CSR 2220- 2.140(3)].

The Board is aware of packaging used by long-term care pharmacies that involve plastic liners within a hard plastic container. These liners must be changed on each initial and refill dispensing.

Q.4 LABELING

Containers dispensed to LTC facilities must comply with all state and federal labeling requirements. [20 CSR 2220- 2.140(5)(D)]. However, Missouri law authorizes the following exceptions for unit-dose containers:

- The drug name/strength, control number, expiration date and manufacturer's name may be included on the package instead of on the container label, and;
- The patient's name and directions do not have to appear on the container label if the LTC facility has a mechanism that will identify the medication each patient is to receive, the personnel administering the medication, and the directions for administration. [20 CSR 2220-2.140(2)(B)].

A bubble card is not considered a unit-dose container and must bear a full prescription label. All drugs dispensed to a LTC facility must have an expiration date on the container.

In the event of a change in directions, a pharmacist may change the container label, however, the pharmacist must personally affix the revised label. Revised prescription labels may not be sent to the LTC facility for their staff to apply. [20 CSR 2220-2.140(2)(B)].

Q.5 RETURN, RE-USE & DISPOSAL

Licensees may receive non-controlled drugs returned from a long-term care facility, hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services under 19 CSR 30-35.020, if:

1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
2) The pharmacist has assurance from a person at the institution/facility responsible for the medication that the drugs were stored in accordance with the manufacturer's recommendations and USP standards; and
3) There is an established mechanism to trace the expiration date and the manufacturer's lot number for the returned medication.

Returned drugs from a long-term care facility, hospital, or hospice facility may be reused if:

1) The drug products are returned sealed in the original manufacturer's tamper-evident packaging; or
2) The drug products were repackaged by a licensed pharmacy or an FDA-registered repackager and are returned sealed in the repackager's tamper-evident packaging, or;
3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication from a long-term care/hospice facility or a hospital must be re-labeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use-date(s) may not be altered.

Patient multi-med paks may not be returned from the LTCF to the pharmacy except for a therapy change/repackaging. (See H.23) Controlled substances may not be returned from a LTC facility.

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